electronic Submission Template And Resource (eSTAR)

Draft Version 0.1 (2020-03-02)

STATUS: eSTAR INCOMPLETE *This eSTAR is incomplete, and will be treated as an improperly prepared eCopy and not reviewed. You will be notified via a standard eCopy Hold email.*

Introduction

This template is intended for use in both constructing an *in vitro* medical device premarket application/submission, and in being a resource of *in vitro* medical device premarket regulations. It contains regulatory information pulled from both International Medical Device Regulators Forum (IMDRF) documents, as well as regulatory documents (e.g., guidance documents).

This template is only used for constructing, not submitting, your application or submission. Directions at the end of the template provide instructions on how to submit it.

Key

A **Red Bar** indicates the associated required question, or a required question in that section, wasn't answered.

A **Green Bar** indicates the associated required question, or all required questions in that section, was answered.

A **Grey Bar** indicates the associated question is optional. Green and Grey Bars act as left borders when present.

? **Blue Help Text Buttons** when clicked display regulatory information pertaining to the question or section heading they immediately follow. Assistive Technology (AT) users including text to speech, will hear "Help Text Button." If activated, the help text windows will open and can be closed by pressing the enter key.

Hover Text Hover text displays information about your application, such as the date an attachment was attached, or, if the section corresponds to an IMDRF harmonized section, the hover text will display the chapter number of the IMDRF Table of Contents.

FAQ

Q: Can FoxIt Phantom be used to complete an eSTAR, or should I use Adobe Acrobat?
A: Use Adobe Acrobat. FoxIt Phantom 9.7.0 has a bug that doesn't save changes properly in PDFs that change dynamically. The bug is only revealed when opened in Adobe Acrobat after an eSTAR PDF is saved in FoxIt.

Q: What if I have several devices in one submission?
A: When a question asks about a device, consider the question as it applies to any device within the submission.

Q: When I click on a bookmark, the view jumps to the beginning of eSTAR. Why did this happen?
A: The bookmarked section is not applicable based on your submission choices, and therefore should be ignored.

Version History

Be sure you are using the latest version of this template when you submit it. If not, you may receive more additional information requests than you otherwise would.

0.1 (2020-03-02): Evaluation version, not for use.

Questions and feedback regarding this template can be sent to eSubPilot@fda.hhs.gov

Built by Patrick Axtell and Lili Duan, FDA/CDRH/OPEQ/ORP

Form FDA 4078 (03/2020)

Application/Submission Type

Take care in providing answers and data to all of the questions in your submission. Any false or misleading statements may be grounds for FDA to put the application on hold before the review commences. FDA may also put the application on hold if an English translation for any documentation provided is not included.

The content of this template complements the FDA reviewer's smart template used in reviewing submissions, and therefore this template will provide the reviewers what they are expecting. This may reduce the number of inconsistencies and omissions in your application/submission documents, and therefore the number of additional information requests the FDA may send to you.

Application Purpose

- (•) Premarket Notification 510(k)
- ( ) De Novo

?

Show Application Introduction

Application Type

- ( ) Traditional
- (•) Abbreviated
- ( ) Special

Show Application Type Introduction

Does this Abbreviated 510(k) rely on a guidance document and/or special controls, or does it rely on an FDA recognized standard?

Application Sub-Type

- ( ) Original
- (•) Supplement
- ( ) Amendment

?

Please enter the parent application/submission number.

Cover Letter

Add Attachment | Attach your Cover Letter ?

Applicant Information ?

Contact

Title | Last Name | First Name

Email | Phone Number | Fax Number

Occupation Title

Company

Company Name

Address - Line 1

Address - Line 2

City | State | Zip | Country: United States of America

Add Correspondent/Consultant

Pre-Submission Correspondence & Previous Regulator Interaction

Are there prior related submissions or regulator interaction for the subject device(s)? Yes ?

Add Submission — Please provide the submission number(s) of prior related submission(s) as defined above, regardless of outcome. If none, type "N/A."

Submission Number | Delete Submission

Add Attachment — Please upload copies of prior regulatory feedback (e.g., letter, meeting minutes, submission feedback) regarding this device and/or data and/or information to support this submission. Please also ensure the uploaded documentation identifies the location in the current submission where any issues are addressed.

Standards ?

Add Standard — Please list the standards used in your submission (if any). If only certain sections were used, or there were deviations, cite these in an attachment. The recognition number is only applicable to certain regulators, see help text. Instead of typing in information, some regulators use drop-downs populated with their recognized Standards.

Organization | Designation Number and Edition/Date | Recognition # | Delete Standard

Title

Are you using this standard for general use, or are you declaring conformity to it? ?

Add Attachment | Standards Details / Supplemental Documentation per ISO/IEC 17050-2 | ?

Organization	Designation Number and Edition/Date	Recognition #	Delete Standard
Title			

Are you using this standard for general use, or are you declaring conformity to it? | ?

Add Attachment | Standards Details / Supplemental Documentation per ISO/IEC 17050-2 | ?

Device Description

Listing of Device(s)

Add Device | Provide the Product Trade Name and (optionally) Model Number/Name

Trade Name | Model Number/Name | Delete Device

Assay and Instrument Information

Device(s) in this submission include ☐ Instrument ☐ Assay

Is the instrument legally marketed in the United States (US)?

Please summarize instrument information below, including instrument name, instrument owner, marketing history in the US and associated submission number(s) if applicable.

Did you make any modification(s) to the legally marketed instrument in order to run the new assay(s)?

Please summarize modification(s) you have made to the legally marketed instrument in order to run the new assay(s).

Add Attachment | Please attach detailed descriptions of instrument modification information if necessary.

Instrument Name

Please summarize Specimen's Identification method on your instrument below.

Please summarize Specimen's Sampling and Handling procedure on your instrument below.

Please summarize Calibration procedure for your instrument below.

Please summarize Quality Control procedure for your instrument below.

General Device Characteristics

Is the device life-supporting or life-sustaining?	Yes
Are there any direct or indirect tissue contacting components?	Yes
• Is the device or a component an implant?	Yes
Does the device use software/firmware?	Yes
• Is the device, or does it contain, digital health technology?	Yes
• Please check the attributes that are applicable to your device.	☐ Cloud Communication ☐ Network connection (active or not) ☒ Wireless communication in any form ☐ USB/serial ports/removable media ☒ Software upgrades (this includes patches) ☐ None of the above
Is the device or a component packaged as sterile?	Yes
The device/system uses or is... (choose all that apply)	☐ a single use device(s), non-sterile or packaged as sterile ☐ a single use device(s), terminal/end user sterilized ☐ a reusable single patient use device(s) ☒ a reusable multi-patient use device(s)
The environment of use of the device/system includes... (choose all that apply)	☒ Professional Healthcare Facility ☐ Home Environment ☐ Magnetic Resonance (MR) Environment ☐ Transport (Ambulatory) Environment ☐ Other Environment
Is the device a combination product?	Yes
• If a Request for Designation (RFD) number exists, please provide the RFD number that established that the device or combination product being submitted here was assigned to CDRH.	
Is the device electrical (battery or wall powered)?	Yes, it is battery and mains powered
• Does the device/system include wireless technology?	Yes
Please check the attributes that are applicable to your device. If none apply, keep all unchecked.	☐ Medical Counter Measures Device ☐ Nanotechnology ☐ Reprocessed Single Use Device ☐ Animal-Derived Material(s)

Description

Please provide a Device Description Summary below, and ensure it includes an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must provide this device description information in the textbox below, in accordance with 21 CFR 807.92(a)(4). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DEVICE DESCRIPTION SUMMARY TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

Add Attachment — Device Description Documentation ?

Add Attachment — Device Pictures, Illustrations, Schematics, and/or Diagrams. Attach a justification if the device does not have a physical form.

Components/Accessories/System

Is the device intended to be marketed with multiple components or accessories? Yes ?

Add Comp./Acc. — List all of the components and accessories to be marketed with the subject device.

Accessory/Component Identification — Delete Comp./Acc.

Please include a description of each component or accessory (see help text for the information we request be included). Please also provide the submission number if the component or accessory was previously cleared, granted or approved (or a statement that it was not). ?

Under section 513(f)(6), are you requesting risk-based classification of an accessory that is not explicitly identified in a classification regulation, or has not been included in a cleared 510(k), approved PMA, or granted De Novo request? ?

Add Attachment — Please attach Component / Accessory Pictures, Illustrations, Schematics, and/or Diagrams

Guidance and Special Controls Adherence

Please identify the attachment(s) and page number(s) of any information provided related to special controls or device specific guidance for this section. Please use the primary product code youprovide in the Classification section below to determine whether a device specific guidance or special controls exists for your device. Type “N/A” if no device specific guidance or special controls exist for your device type. If you type “N/A,” and special controls or device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

Submission Number *(if known)*

Device Name

Indications for Use *(Describe)*

Hover over each field on this page to view help text. It is recommended that you also include age, sex, gender, race and/or ethnicity information for which your device(s) is indicated in your Indications for Use, if applicable.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Classification

Add a primary product code and any associated product codes below. You may type in the primary product code directly (only the product code field is required) or you may filter down by choosing first a medical specialty, regulation, then product code. If a device specific guidance is available for the product code, the guidance name and web link will be displayed. Use the Product Classification Website resource in the help text to obtain information about your product code and check the regulation text for any special controls that need to be considered (e.g, PAE and 21 CFR 890.3450). ?

Medical Specialty	Clinical Chemistry
Regulation	862.1175 - Cholesterol (total) test system
Product Code	CHH (Class 1) - Enzymatic Esterase--Oxidase, Cholesterol

The primary product code of your device indicates a device specific guidance document is available to aid you in preparing a comprehensive submission. The document entitled "Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory, and Home Use" is available at the link below. If you have any questions about applicability of this guidance, please contact the CDRH review Office.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-510ks-cholesterol-tests-clinical-laboratory-physicians-office-laboratory-and-home-use

Associated Product Code(s) ?

Predicates and Substantial Equivalence

Predicate and Reference Devices

?

Primary Predicate

Is this a Preamendments or Exempt device without a submission number?	Yes	?
Predicate Device Trade Name		
Predicate Device Primary Product Code		
Medical Specialty		
Regulation		
Product Code		

Add Predicate/Reference Device

Delete Predicate/Reference Device

Substantial Equivalence Comparison

If the device has different indications for use in comparison to the predicate device(s), describe why the differences do not constitute a new intended use. If the indications for use are the same, state this in the text box below.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), and the Indications are different in comparison to your predicate device(s), you must include the information from 21 CFR 807.92(a)(5) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

THEREFORE, ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE RATIONALE TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

?

Help Text

If the device has the same technological characteristics (i.e., design, material, chemical composition, principle of operation, energy source, etc.) as the predicate device(s) identified above, include a summary in the memo box below of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), include a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified above.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include the information from 21 CFR 807.92(a)(6) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

THEREFORE, ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DESCRIPTION TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

?

Help Text

Add Attachment	Please attach your Substantial Equivalence Comparison in tabular format. Please ensure the table(s) includes a comparison of the Indications for Use as well as a comparison of the pertinent technology characteristics of your device and your predicate device(s).	?

Performance Testing

Analytical Performance

Did you perform Precision (Repeatability/Reproducibility) Study?	Yes	?
Add Attachment	Please attach documentation that includes details of the Precision (Repeatability/ Reproducibility) Study performed with your device, including associated study protocol(s), study results and line data.	?
Did you perform Linearity Study?	Yes	?
Add Attachment	Please attach documentation that includes details of the Linearity Study performed with your device, including associated study protocol(s), study results and line data.	?
Did you perform Analytical Sensitivity/Detection Limit(s) Study?	No	?
Provide a statement of why Analytical Sensitivity/Detection Limit(s) Study is not applicable.		
Do you have Assay Measuring Range information to include in this submission?	No	?
Provide a statement of why Assay Measuring Range information is not applicable.		
Did you perform Analytical Specificity/Interference Study?	Yes	?
Add Attachment	Please attach documentation that includes details of the Analytical Specificity/ Interference Study performed with your device, including associated study protocol(s), study results and line data.	?
Did you perform Assay Cut-Off Study?	Yes	?
Add Attachment	Please attach documentation that includes details of the Assay Cut-Off Study performed with your device, including associated study protocol(s), study results and line data.	?
Do you have Traceability information to include in this submission?	No	?
Provide a statement of why the Metrological Traceability information is not applicable.		
Do you have Stability information to include in this submission?	No	?
Provide a statement of why Stability Study is not applicable.		

Do you have other Analytical Performance Supportive Data to include in this submission? Yes ?

Provide a brief summary of the other Analytical Performance Supportive Data you included in this submission.

Add Attachment Please attach documentation that includes details of other Analytical Performance Supportive Data obtained with your device.

Comparison Studies

Did you perform Method Comparison Study? Yes ?

Add Attachment Please attach documentation that includes details of Method Comparison Study performed with your device, including associated study protocol(s), study results and line data. ?

Did you perform Matrix Comparison Study? No ?

Provide a statement of why Matrix Comparison Study is not applicable.

Clinical Studies

Do you have Clinical Sensitivity and/or Clinical Specificity to include in this submission? Yes ?

Add Attachment Please attach documentation that includes details of Clinical Sensitivity and/or Clinical Specificity for your device, including associated study protocol(s), study results and line data. ?

Do you have Clinical Cut-Off information to include in this submission? No ?

Provide a statement of why Clinical Cut-Off information is not applicable.

Do you have other Clinical Supportive Data to include in this submission? Yes ?

Provide a brief summary of the other Clinical Supportive Data you included in this submission.

Add Attachment Please attach documentation that includes details of Other Clinical Supportive Data obtained with your device. ?

Reference Range/Expected Values ?

Do you have Reference Range/Expected values information to include in this submission?	Yes
Add Attachment	Please attach documentation that includes details of Reference Range/Expected values information for your device. ?

Compliance with Good Clinical Practice for Supporting Clinical Investigations

Do you have clinical investigation(s) in this submission that is subject to the requirements governing FDA acceptance of data from clinical investigations? Click the Help Text button for more information.	Yes ?
Where were the supporting clinical investigation(s) included in this submission conducted?	Clinical investigations were conducted at BOTH US and OUS sites
Add Attachment	For each clinical investigation with US sites included in this submission, please attach a statement of compliance with 21 CFR parts 50, 56, and 812 and/or a rationale for not complying with those regulations.
Add Attachment	For each clinical investigation with OUS sites included in this submission, please attach: 1) A statement of compliance with GCP per 21 CFR 812.28(a)(1), and supporting information as described in parts 21 CFR 812.28(a)(2) and (b), and/or 2) A rationale for not providing the above referenced statement of compliance with GCP or supporting information, and/or 3) A waiver request in accordance with 21 CFR 812.28(c)

Animal Testing ?

Was Animal Testing used in order to demonstrate substantial equivalence?	Yes
Provide the predicate device submission number (e.g., K180001) that is the best comparator for the testing attached below.	
Add Attachment	Please attach documentation that includes details of the animal testing performed with your device. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.
Add Attachment	Please include a study protocol which includes all elements as outlined in 21 CFR 58.120. ?
Add Attachment	Please include a final study report which includes all elements as outlined in 21 CFR 58.185. ?
Please provide a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, please explain why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination. ?	

Performance Testing Summary

If the determination of substantial equivalence is also based on an assessment of performance data, we recommend you fill out the text boxes below. If no testing was necessary, state this in the respective field below. If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include this information, in accordance with 21 CFR 807.92(b). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

THEREFORE, ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE SUMMARY TEXTBOXES BELOW.

Provide a brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. If any guidance documents or FDA recognized consensus standards were used/referenced for testing, cite these here. ?

Provide a summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. Refer to the help text for a list of the details we recommend be included regarding the subjects and clinical evidence. If no clinical data were necessary, please type "Not Applicable." (There should not be any patient identifier information in the summary.) ?

State the conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified above. ?

Guidance and Special Controls Adherence

Please identify the attachment(s) and page number(s) of any information provided related to special controls or device specific guidance for this section. Please use the primary product code you listed in the Device Description/Classification section above to determine whether a device specific guidance or special controls exists for your device. Type “N/A” if no device specific guidance or special controls exist for your device type. If you type “N/A,” and special controls or device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

Add Attachment	Since you indicated that this is an Abbreviated 510(k) that relies on a Guidance Document or Special Controls, please attach a summary report below that describes how the guidance and/or special control(s) were used to address the risks associated with the particular device type. (If an applicant elects to use an alternative approach to address a particular risk, sufficient detail should be provided to justify that approach.)

EMC, Wireless, Electrical, Mechanical and Thermal Safety

Based on the answers provided in the Device Description section, EMC and wireless technology information is needed.

Electromagnetic Compatibility (EMC)

How many devices/accessories/components were subjected to EMC testing (maximum of 4)? 1

EMC Test 1

Device Specific EMC Considerations

Could loss of device function due to electromagnetic interference (EMI) pose hazards that could result in death or permanent impairment of bodily function or structure or require surgical intervention? Yes

Was testing performed according to a recognized edition of IEC 60601-1-2? Please attach any summaries/reports in the "EMC, Wireless & EMT Documentation" section below.

Please list the Essential Performance that is specific to the device, or provide a rationale why the device has no Essential Performance, in the space below.

Please provide the page number(s) in the summary/report that include pass/fail criteria specific to the device that are based on the device functions, intended use, and Essential Performance. It is recommended that all device functions that are associated with basic safety or Essential performance be tested and include device-specific pass/fail criteria.

If the device under test is not the final finished version, please provide a justification for why the differences don't affect EMC. If the device under test is the final finished version, please state this.

Please provide the page number(s) in the summary/report that include a description of the device/system configuration that adequately addresses and monitors the specific functions of the device that were tested.

If the wireless technology is used to fulfill the intended use of the device, was it turned on and actively transmitting during the immunity testing?

EMC Emissions and Immunity Test Information

Please provide the page number(s) in the summary/report where the CISPR 11 emission limits are located.

Please provide the page number(s) in the summary/report where the IEC 61000-4-2 electrostatic discharge (ESD) immunity test levels and test results (or observations) are located.		?
Please provide the page number(s) in the summary/report where the IEC 61000-4-3 radiated RF electromagnetic field immunity test levels and test results (or observations) are located.		?
Please provide the page number(s) in the summary/report where the proximity field immunity test levels and test results (or observations) from IEC 60601-1-2 Sec 8.10 and Table 9 are located.		
Please provide the page number(s) in the summary/report where the IEC 61000-4-8 power frequency magnetic field immunity test levels and test results (or observations) are located.		?
Please provide the page number(s) in the summary/report where the IEC 61000-4-6 conducted disturbances induced by RF fields immunity test levels and test results (or observations) are located.		?
Please provide the page number(s) in the summary/report where the IEC 61000-4-4 electrical fast transient/burst immunity test levels and test results (or observations) are located.		?
Please provide the page number(s) in the summary/report where the IEC 61000-4-5 surge immunity test levels and test results (or observations) are located.		?
Please provide the page number(s) in the summary/report where the IEC 61000-4-11 voltage dips, short interruptions, and voltage variations immunity test levels and test results (or observations) are located.		?

If there were any degradations or observations noted during the testing, describe how the device(s) continued to meet the essential performance during these degradations or observations.

Emitters, Allowances, Deviations & Modifications

If any of the referenced standard's allowances were used during the testing (e.g., lowered ESD immunity), please provide these below. ?

If there were any deviations from the referenced standard, please describe these below.

Add Attachment	Please add an attachment that includes descriptions of all modifications, as well as a statement indicating that all changes or modifications will be incorporated in the device intended for marketing. Not providing an attachment indicates no modifications were made in order to pass any of the EMC tests. In addition, be sure you include an adequate assessment on whether these modifications might impact other aspects of the device (e.g., performance, biocompatibility). It is recommended that the attachment contain information to demonstrate that the modifications would have no impact on the other aspects or that the modified device was used for the other performance tests.
Add Attachment	Please add an attachment that addresses the risks associated with exposure to specific common EM emitters that are not adequately addressed by IEC 60601-1-2 (risk analysis with appropriate mitigation that might include testing or labeling) foreseeable in the intended use vicinity (e.g., RFID, security systems such as metal detectors and EAS, diathermy).

Device Labeling

Please specifically cite the attachment(s) and page number(s) where the environment(s) of use for which the device/system is suitable and information analogous to the Guidance Tables 1 through 8 from the 3rd edition of IEC 60601-1-2 (e.g., recommended separation distances, appropriate EM environments) are located in the labeling.	
Please specifically cite the attachment(s) and page number(s) where the performance of the device that was determined to be Essential Performance and a description of what the operator can expect if the Essential Performance is lost or degraded due to electromagnetic disturbances are located in the labeling.	
Please specifically cite the attachment(s) and page number(s) where the compliance for each emissions and immunity standard or test specified by the collateral standard (e.g., emissions class and group and immunity test level). are located in the labeling.	
Please specifically cite the attachment(s) and page number(s) where any deviations from the collateral standard and allowances used are described in the labeling. Type "N/A" if not applicable.	

Wireless Technology

How many separate wireless functions are there (maximum of 5)? 1

Wireless Function 1

Wireless Link

Specify the device function to be implemented wirelessly and risks associated with failure, disruption, or delay of communication. Please consider inherent risks due to complete wireless communication loss as well as risks identified by the sponsor during their risk analysis process. Additionally, please consider the safeguards and redundancies that might be built into the wireless function when considering the risk. (If more than one function is specified, please use the dropdown directly above to indicate the number of functions, and address each separately)

Please choose the most appropriate choice for the risk of the wireless function (which may not be the same as the risk of the device). The risks of the wireless function are defined in AAMI TIR69.

Negligible: failure of the wireless function could result, as a maximum, in inconvenience or temporary discomfort. Commonly, this category of function is related to no foreseeable hazards to patients or users. This includes data that, if delayed, disrupted, or lost, will result at most as an inconvenience but with no risk to patient safety.

Minor (Tier 3): failure of the wireless function could result in temporary injury or impairment not requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, does not significantly impact the patient's health or medical device's intended use. These can include hazards associated with minor harms or contributing factors in decision-making.

Moderate (Tier 2): failure of the wireless function could result in injury or impairment requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, could result in a delay of therapy.

Major (Tier 1): failure of the wireless function could result in death or serious injury. This includes critical data for patient health, critical therapy, high priority alarms, remote programming, and other information and signals necessary for life-sustaining or life-supporting activities.

Major (Tier 1) ?

What is the Quality of Service (QoS) of the device? ?

Please select all the technologies that apply to this wireless function:

☐ Bluetooth ☐ Wifi ☐ ZigBee ☐ RFID ☐ Cellular ☐ Other

Environment of Use

Are other wireless products able to connect and transmit to the wireless network of the subject device? ?

Wireless Coexistence Testing

Add Attachment Coexistence Testing ?

Please describe the Functional Wireless Performance (FWP). ?

Please describe the pass/fail criteria for the FWP and be sure to clarify how each criterion was quantified and measured. ?

Was the coexistence testing conducted to Tier 1 (per the risk category chosen above)?	?
Were the Equipment Under Test (EUT) and its companion device both exposed to the unintended signal?	?
Was the functional wireless performance (FWP) maintained during the testing? If not, were adequate mitigations provided?	?

RF Wireless Labeling

Please specifically cite the attachment(s) and page number(s) where the wireless specifications are included (QoS, frequency, power, operating distance, security).	?
Please specifically cite the attachment(s) and page number(s) where the risks and mitigations about wireless use included (precautions for proximity to other wireless products and recommendations for separation distances from such products).	
If device degradations were observed during coexistence testing, please specifically cite the attachment(s) and page number(s) where the labeling has information about how to mitigate this issue. Type "N/A" if not applicable.	?

Electrical, Mechanical, and Thermal Summary

Please summarize the Electrical, Mechanical and Thermal Testing of your device, or summarize why testing was not needed. Please ensure any standards cited here are also cited in the Standards subsection within the first part of this template (located after Applicant, Correspondent, and Pre-Submission Correspondence).	?

EMC, Wireless, & EMT Documentation

Add Attachment	Please attach the documentation pertaining to the Electromagnetic Compatibility Testing (e.g., EMC test reports/summaries), Safeguards, Wireless Testing, and Electrical, Mechanical and Thermal Testing of your device.

Software/Firmware & Cybersecurity/Interoperability

Based on the answers provided in the Device Description section, software and cybersecurity information is needed.

Software

Software Level of Concern (LOC) Determination ?

Does the Software qualify as Blood Establishment Computer Software? ?	
Is the Software intended to be used in combination with a drug or biologic?	
Is the Software an accessory to a medical device that has a Major LOC?	
Prior to mitigation of hazards, could a failure of the Software result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following: a) Does the Software control a life supporting or life sustaining function? b) Does the Software control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators? c) Does the Software control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury? d) Does the Software provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death? e) Does the Software provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	
Is the Software an accessory to a medical device that has a Moderate LOC?	
Prior to mitigation of hazards, could a failure of the Software result in Minor Injury, either to a patient or to a user of the device?	
Could malfunction of, or a latent design flaw in, the software lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	
Based on the questions answered above, your LOC is determined to be:	

The software documentation below is recommended for the level of concern specified. Click on the blue help text buttons for details about what is recommended in the documentation for each.

Software Description ?

Add Attachment	Please attach a description of the software / firmware that includes: a textual description of the software / firmware, the version number of the software / firmware, the input parameters (user inputs), and the output parameters (device actions).

Software Documentation

Add Attachment	Device Hazard Analysis	?
Add Attachment	Software Requirements Specifications (SRS)	?
Add Attachment	Architecture Design Chart	?
Add Attachment	Software Design Specifications (SDS)	?
Add Attachment	Traceability Analysis/Matrix	?
Add Attachment	Software Development Environment Description	?
Add Attachment	Verification & Validation Testing	?
Add Attachment	Revision Level History	?
Add Attachment	Unresolved Anomalies	?

Cybersecurity ?

Risk Management ?

Add Attachment	Threat Modeling	?
Add Attachment	Cybersecurity Vulnerabilities/Risks	?
Add Attachment	Cybersecurity Controls	?
Add Attachment	Traceability Matrix	?

Plan for Continuing Support

Add Attachment	Plan for Continuing Support	?

Plan for Malware-Free Shipping

Add Attachment	Plan for Malware-Free Shipping	?

Cybersecurity Labeling

Add Attachment	Cybersecurity Labeling	?

Interoperability

How many Electronic Interfaces are there?	1	?

Electronic Interface 1

Name the Electronic Interface	
Is the electronic interface inactive (i.e. not meant to connect, exchange, or use data with or from other medical devices, products, technologies, or systems)?	

Biocompatibility

Based on the answer provided in the Device Description section, biocompatibility information is needed.

Tissue Contacting Products/Components/Materials

How many tissue contacting products/components/materials are there? 1

Tissue Contacting Material 1

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

Please state the exact name and any identifiable information for the particular material used.

If color additives are included, please identify them here.

Choose intended contact of the particular material. Direct

Please provide the FDA submission number (e.g., K010001) if you are aware of a previously submitted device using the same material with similar nature of contact.

If you are aware of a previously submitted device using the same material with similar nature of contact, please provide any pertinent information to compare your device to the device/test article in the previously submitted biocompatibility assessment. Any changes in formulation, processing, sterilization, geometry (including surface characteristics) and the addition of other chemicals (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents) should be addressed to support use of the previous biocompatibility assessment (e.g., no additional biocompatibility testing is necessary).

Is there a potential for repeat exposure? Yes

If there is potential for repeat exposure, please describe the circumstances here.

Choose the type of tissue contact of your tissue contacting material.

Duration of Contact

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility tests performed for these endpoints. If you used an alternative test method than the options provided, or

you did not conduct the test, please provide an explanation or justification (e.g., the material is identical in formulation and processing to predicate material) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.**

Biocompatibility Reports and Documentation

Add Attachment	Please attach any documentation (e.g., test reports) pertaining to the biocompatibility of your device. If no test reports were attached, please attach a rationale explaining why testing is not necessary.

Reprocessing, Sterility, and Shelf-Life

Since the answers you provided in the Device Description section indicate reprocessing and sterility information is needed, be aware that the Reprocessing section covers devices that are sterilized by the end user, while the Sterility section covers devices that are packaged as sterile.

Reprocessing

Are cleaning or disinfection or sterilization instructions included in the labeling?	Yes
How many different sets of reprocessing instructions are included (maximum of 4):	1

Reprocessing Instructions 1

Please identify the device(s), and/or accessory(ies), and/or component(s) that are covered by this set of instructions.

Please specifically cite the attachment(s) and page number(s) where the cleaning/disinfection instructions are located in the labeling.

Cleaning Instructions

Some devices (e.g., some orthopedic implants) are provided clean and are only subjected to end-user sterilization. Is the device single-use and provided clean so that cleaning instructions are unnecessary and are not included in the labeling?	
Is a Point-of-Use care instruction included (e.g., to prevent drying)?	
Please specifically cite the attachment(s) and page number(s) where the disassembly/reassembly instructions are located. Type "N/A" if not applicable. (Note: If disassembly of the device is necessary for adequate reprocessing, specific instructions for disassembly and reassembly should be provided.)	
Please specifically cite the attachment(s) and page number(s) where the instructions to “thoroughly clean” the device (or similar text) are included in the labeling? Type "N/A" if not applicable.	
If the labeling recommends special accessories for cleaning, please specifically cite the attachment(s) and page number(s) or section(s) where the instructions include details on special accessories (e.g., brush size, brush materials, detergent category) if applicable. Type "N/A" if not applicable.	
Please specifically cite the attachment(s) and page number(s) where the instructions include how to use accessories (e.g., medical washers) or reference accessory labeling. Type "N/A" if not applicable.	
Please specifically cite the attachment(s) and page number(s) where the instructions include specifications for cleaning (e.g., times, temperatures, cleaning agents, dilution/concentration, rinses including duration or volume, time, and appropriate final rinse water quality). Type "N/A" if not applicable.	

Please specifically cite the attachment(s) and page number(s) where the instructions include: 1) visual inspection, 2) an inspection endpoint (e.g., “no visual contamination”), and 3) steps the user should repeat if the endpoint is not met.	
Please specifically cite the attachment(s) and page number(s) where the instructions include mid-process drying (i.e., drying after cleaning) recommendations. Type "N/A" if not applicable.	
If lubricating agents are recommended, do the reprocessing instructions recommend the use of a class of lubricating agent (e.g., water soluble lubricants) after cleaning that is compatible with the medical device, its intended use, and with any subsequent processing steps such as sterilization.	
Please specifically cite the attachment(s) and page number(s) where the instructions include reuse life limits (e.g., number of uses, inspection specifications or performance tests). Type "N/A" if not applicable.	

Microbicidal Process

The questions below are intended to help you determine the appropriate reprocessing steps after cleaning, if applicable. General recommendations are described in Criterion 3 of FDA's Reprocessing Guidance, and are summarized below:

- Devices that contact normally sterile areas of the body should be sterilized.
- Devices that contact mucosal membranes or non-intact skin should be (steam) sterilized, unless the device design does not permit steam sterilization (e.g., device materials cannot withstand sterilization). In that instance, devices should be high-level disinfected.
  - Optional chemical sterilization (such as ethylene oxide or hydrogen peroxide sterilization) instructions may also be provided for devices that are high-level disinfected.
- Low/intermediate-level disinfection or cleaning alone may be acceptable for devices that contact intact skin or do not directly contact the patient.

These are general principles, and there may be exceptions.

Which types of microbicidal process instructions are present in these instructions?	High level disinfection and/or liquid chemical sterilization

High-Level Disinfection/Liquid Chemical Sterilization

Please specifically cite the attachment(s) and page number(s) where the instructions recommend use of an FDA-cleared high-level disinfectant (HLD) or liquid chemical sterilant (LCS).	
Please specifically cite the attachment(s) and page number(s) where the instructions recommend following HLD/LCS manufacturer’s instructions.	
Please specifically cite the attachment(s) and page number(s) where the instructions recommend complete immersion in HLD/LCS solution, including contact with all lumens.	
Please specifically cite the attachment(s) and page number(s) where the instructions include instructions for rinsing, drying, and storage.	

Technically Feasible, Understandable, and Comprehensive ?

Be sure the reprocessing instructions can be understood and reasonably implemented by the end user in the intended reprocessing location. If a device is intended to be reprocessed in the home, then reprocessing steps should include products that are available for use in the home (not sterilizers or high-level disinfectants) and are appropriate for the reprocessing procedure (e.g., baby bottle sanitizers are not recommended for reprocessing most medical devices).

If the device is initially supplied non-sterile to the user and specifies to sterilize the device before use, the device should be prominently labeled “Non-sterile” directly on the individual device label (e.g., as opposed to only on the shipper carton).

When warranted, the labeling should include special warnings or precautions about potential damage to the device from improper reprocessing procedures. These may be related to user safety or emphasize conditions that could significantly alter the safety or effectiveness of reprocessing or performance of the device. For example, some devices may have unsealed seams/crevices through which excessive liquid disinfectant could reach the interior of the device and damage it. In such cases, the labeling should caution users about this potential hazard and provide specific use instructions to prevent it, such as avoiding the application of excess liquid to the device. Not all devices may need this type of warning in the labeling. If you are unsure, check if similar devices have labeling with this type of warning.

Sterility

How many sterilization methods are there (maximum of 4)? 1

Sterilization Method 1

Identify the device(s) / accessory(ies) / component(s) that is sterilized.

What is the Sterilization Method?

What standard(s) were used for validation?

What is the Sterility Assurance Level (SAL)?

If a device within the submission should be "Non-Pyrogenic," or if you are asserting a device is "Non-Pyrogenic," what is the pyrogenicity test method?

Please provide a description of the packaging, the materials used, and a description of the package test methods.

Guidance and Special Controls Adherence

Please identify the attachment(s) and page number(s) of any information provided related to special controls or device specific guidance for reprocessing or sterility. Please use the primary product code you listed in the Classification section above to determine whether a device specific guidance or special controls exists for your device. Type “N/A” if no device specific guidance or special controls exist for your device type. If you type “N/A,” and special controls or device specific guidance exists that requests information covered by these review sections, the time-line for review of your file may be affected.

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls regarding reprocessing or sterility, provide a rationale for this alternative approach below.

Shelf-Life

Does your device have a shelf-life?	Yes	?
What is the proposed shelf life?		

Please include a summary of the methods used to establish that device sterility/performance will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable.

Reprocessing, Sterility, and Shelf-Life Documents

Add Attachment	Please attach any Sterility, Cleaning, Shelf-Life and Reuse documentation that you believe is pertinent to the review of your device. Choose the attachment type in the dropdown for each attachment.	?

Labeling

You must submit proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied (21 CFR 807.87(e)). We also strongly recommend you consult standard AAMI ANSI ES60601-1:2005(R)2012 Section 7 for applicable labeling that may be important for your device if it is electrical (consult ISO 14708-1 instead for implantable components).

General Labeling

If a symbols glossary was used, please specifically cite the attachment and page number where it is located in the labeling (type "N/A" if not used). Be aware that if a glossary was not used, the symbols should be described in adjacent text (if applicable, see Help Text).

?

What is the Magnetic Resonance (MR) safety status for the device(s) in the submission?

?

Package Labeling

Add Attachment

Please attach copies of packaging that demonstrate the labeling of any applicable packaging used in the transportation of the device. This includes, but is not limited to, the device packaging and sterile packaging. This does not include shipping labels.

Package Insert / Instructions for Use

Add Attachment

Please attach copies of the User Instructions, Inserts, Directions for Use and/or Instructions for Use that are intended for use with your device. This includes instructions that may be downloaded or viewed on a website.

Other Labeling

Add Attachment

Choose the attachment type in the dropdown for each attachment. Click the help text button to the right for an explanation of each option.

?

Specific Labeling

Please specifically cite the attachment and page number where the Indications for Use exists in the labeling.

Please specifically cite the attachment and page number where the name and place of business of the manufacturer, packer, or distributor is located.

?

Guidance and Special Controls Adherence

Please identify the attachment(s) and page number(s) of any information provided related to special controls or device specific guidance for this section. Please use the primary product code you listed in the Classification section above to determine whether a device specific guidance or special controls exists for your device. Type “N/A” if no device specific guidance or special controls exist for your device type. If you type “N/A,” and special controls or device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

References

Is literature referenced in the submission? Yes ?

Add Attachment Please add legible reprints or a summary of each article in English.

Please include a discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.

Administrative Documentation

Add Attachment	Executive Summary	?
Add Attachment	Financial Certification and Disclosure Statement (Form FDA-3454)	?
Add Attachment	Clinical Trials Certification Form (Form FDA-3674)	?

The Truthful and Accurate Statement is required for all 510(k) types (21 CFR 807.87(k)). It is a legally binding statement that provides additional assurance that the data submitted in the 510(k) is truthful and accurate and that no material fact has been omitted. This statement must be signed by a responsible person of the applicant company; it cannot be signed by a consultant to the applicant. If you are a responsible party of the 510(k) owner, this statement will be automatically produced and signed with your electronic signature (click the Administrative Documentation help text above to learn how to obtain an electronic signature). Ensure the signature you use to sign this application is for the owner of the 510(k), or, if you are not a responsible party of the 510(k) owner, attach a Truthful and Accurate statement below.

Weblink: Truthful and Accurate Statement

Are you a responsible party of the owner for this 510(k) Premarket Notification, and will you be electronically signing this application for submission?	Yes
Would you like to attach a 510(k) Statement or Summary? If you do not attach a 510(k) Statement or Summary, and you provided all of the data necessary to produce a 510(k) Summary, then a 510(k) Summary will be produced by this form. If you choose to submit a 510(k) Summary instead of a 510(k) Statement, be aware that the data provided in the 510(k) Summary will be publicly available if your 510(k) is cleared. As a result, be sure no confidential information is included in the 510(k) Summary. If you choose to submit a 510(k) Statement, be aware that you must provide summary information to anyone who requests it.	No

Add Attachment	Please attach your User Fee form here.	?
Please enter in the User Fee Payment Identification Number.		?

Show User Fee Introduction

Truthful & Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as (ADD THE POSITION HELD IN COMPANY) of (ADD COMPANY NAME), I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Date Signed:

510(k)#: For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

510(k) Summary

Contact Details 21 CFR 807.92(a)(1)

Applicant Name	
Applicant Address	
Applicant Contact Telephone	
Applicant Contact	
Applicant Contact Email	

Device Name 21 CFR 807.92(a)(2)

Device Trade Name	
Common Name	Cholesterol (total) test system
Classification Name	Enzymatic Esterase--Oxidase, Cholesterol
Regulation Number	862.1175
Product Code	CHH

Legally Marketed Predicate Devices 21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code

Device Description Summary 21 CFR 807.92(a)(4)

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

Indications for Use Comparison 21 CFR 807.92(a)(5)

Technological Comparison 21 CFR 807.92(a)(6)

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

510(k) Supplement

Is this a response to an Additional Information request?	Yes

Additional Information

Changes that are necessary to resolve deficiencies should be made in the respective section. For example, if additional Sterilization information will be provided to resolve a deficiency, this documentation should be added to the Sterilization documentation that is already present. If attachments need to be updated, remove the old attachments and replace them with the new attachments (be sure to give new attachments a different name in comparison to the old attachments to ensure they are distinguished). Data that are typed in can also be modified. If there are documents that will be used to justify a response, but that do not fit in with any section, include it within a ZIP package alongside this PDF. Please note that all previous data and attachments will remain in the FDA database. These old data will not be considered the up-to-date data in our final review.

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

Add Response | Delete Response

Verification

The following sections are complete:
Classification

The following sections are incomplete:
Application/Submission Type
Cover Letter
Administrative Information
Device Description
Indications for Use
Predicates and Substantial Equivalence
Performance Testing
EMC, Wireless, Electrical, Mechanical and Thermal Safety
Software/Firmware & Cybersecurity/Interoperability
Biocompatibility
Reprocessing, Sterility, and Shelf-Life
Labeling
References
Administrative Documentation
510(k) Supplement

Export Data	You can export the data in this eSTAR in XML format by clicking the Export Data button to the left. Attachments are not included.
Import Data	You can import the XML data of another eSTAR into this eSTAR by clicking the Import Data button to the left, and choosing the XML file. Attachments will not be imported.

Registration and Listing

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration.

Congress has authorized FDA to collect an annual establishment registration fee for device establishment registrations. A detailed list of all those establishment types that have to pay the registration fee can be found at the Who Must Register, List and Pay the Fee website. There are no reductions in annual establishment registration fees for small businesses or any other group.

Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also submit the FDA premarket submission number (510(k), PMA, PDP, HDE).

Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Knowing where devices are made increases the nation's ability to prepare for and respond to public health emergencies.

For details about registering and listing your device, please see the Device Registration and Listing website. If you encounter an issue or wish to contact us regarding the Electronic Registration and Listing System (FURLS), please send an email to reglist@cdrh.fda.gov.

Submittal Directions

IVD eSTAR Pilot

If you are part of the eSTAR Pilot, you only need to submit this eSTAR PDF with embedded attachments on a CD, DVD, or USB Drive (SD cards are not accepted) with a printed cover letter to our Document Control Center. As an example, an acceptable submission package, as part of this pilot only, would consist

of a printed cover letter accompanying a USB drive with only this eSTAR PDF on it. **If you are part of the eSTAR Pilot, the submission does not need to be eCopy compliant, nor does the eSTAR PDF need to be zipped and placed in a MISC FILES folder.**