

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved: OMB No. 0910-0120
Expiration Date: XXXXXX XX, 201X
See PRA Statement on last page.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number <i>(If known)</i>
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SECTION A TYPE OF SUBMISSION

<p style="text-align: center;">PMA & PDP</p> <input type="checkbox"/> Original <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report (annual or PAS) <input type="checkbox"/> Report Amendment <input type="checkbox"/> Other: <input type="checkbox"/> Premarket Report (reprocessed SUD) <input type="checkbox"/> Licensing Agreement	<p style="text-align: center;">PMA/PDP Supplement</p> <input type="checkbox"/> 180 day - PAS protocol or labeling change, location change, trade name change <input type="checkbox"/> 180 day - Design or labeling change <input type="checkbox"/> Special CBE <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-day Notice <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA/PDP Supplement	<p style="text-align: center;">510(k)</p> <input type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input type="checkbox"/> 3rd Party Traditional <input type="checkbox"/> 3rd Party Special <input type="checkbox"/> 3rd Party Abbreviated <input type="checkbox"/> Dual Track (Dual 510(k) and CLIA Waiver by Application) <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<p style="text-align: center;">CLIA</p> <p>CLIA Categorization Record (CR) <input type="checkbox"/> Original <input type="checkbox"/> Amendment</p> <p>CLIA Waiver by Application (CW) <input type="checkbox"/> Original <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement</p>	<p style="text-align: center;">Q-Submission</p> <input type="checkbox"/> Pre-Submission <input type="checkbox"/> Informational Meeting <input type="checkbox"/> Submission Issue Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Study Risk Determination <input type="checkbox"/> Other <i>(Specify below)</i>
<p style="text-align: center;">IDE</p> <input type="checkbox"/> Original IDE: <input type="checkbox"/> Amendment to Original IDE <input type="checkbox"/> Supplement: <input type="checkbox"/> Amendment to Supplement <input type="checkbox"/> Report: <input type="checkbox"/> Amendment to Report	<p style="text-align: center;">HDE</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment to Original <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> HDE Supplement: <input type="checkbox"/> 75-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> Special CBE <input type="checkbox"/> Amendment to Supplement	<p style="text-align: center;">Class II Exemption Petition</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information <p style="text-align: center;">Emergency Use Authorization</p> <input type="checkbox"/> Original <input type="checkbox"/> Supplement <input type="checkbox"/> Amendment <input type="checkbox"/> Report	<p style="text-align: center;">De Novo</p> <input type="checkbox"/> Original: <input type="checkbox"/> Direct <input type="checkbox"/> Post-NSE <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <p style="text-align: center;">Pre-Emergency Use Authorization</p> <input type="checkbox"/> Original <input type="checkbox"/> Supplement <input type="checkbox"/> Amendment	<p style="text-align: center;">Other Submission</p> <input type="checkbox"/> 513(g) <input type="checkbox"/> Appeal <input type="checkbox"/> Other <i>(Briefly describe submission below)</i>

Expanded Access to Devices

Compassionate Use Request **NOT associated with an IDE**
 Follow-up Report for Compassionate Use **NOT associated with an IDE**
 Emergency Use Follow-up Report **NOT associated with an IDE**

SECTION B APPLICANT / SPONSOR

Company/Institution Name		Establishment Registration Number/FEI <i>(if known)</i>	
Street Address		City	
State/Province	ZIP/Postal Code	Country	
Contact Name		Contact Title	
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i>	
Fax Number <i>(including area code)</i>		Contact Email Address	

SECTION C OFFICIAL CORRESPONDENT (e.g., may be a consultant and/or 510(k) Third Party) (if different from Section B)

Company/Institution Name		Establishment Registration Number/FEI (if known)	
Street Address		City	
State/Province	ZIP/Postal Code	Country	
Contact 1 Name		Contact 1 Title	
Contact 1 Division Name (if applicable)		Contact 1 Phone Number (including area code)	
Contact 1 Fax Number (including area code)	Contact 1 Email Address		
Contact 2 Name		Contact 2 Title	
Contact 2 Division Name (if applicable)		Contact 2 Phone Number (including area code)	
Contact 2 Fax Number (including area code)	Contact 2 Email Address		
Contact 3 Name		Contact 3 Title	
Contact 3 Division Name (if applicable)		Contact 3 Phone Number (including area code)	
Contact 3 Fax Number (including area code)	Contact 3 Email Address		

To add another set of Section C items, please click on the button to the right. May be repeated as needed.

Add Section C

SECTION D INTENDED USE POPULATION

Check all that apply.

<input type="checkbox"/> Adults Only (greater than 21 years of age)	<input type="checkbox"/> Neonate/Newborn (birth through 28 days)	<input type="checkbox"/> Other (Specify below)
<input type="checkbox"/> Adults and Pediatrics	<input type="checkbox"/> Infant (from 29 days to 2 years of age)	
	<input type="checkbox"/> Child (from 2 years to 12 years of age)	
	<input type="checkbox"/> Adolescent (from 12 years to 18 years of age)	
	<input type="checkbox"/> Transitional Adolescent A (18 through 21 years of age)	
	<input type="checkbox"/> Transitional Adolescent B (18 through 21 years of age)	

SECTION E PRODUCT INFORMATION – APPLICABLE TO ALL SUBMISSIONS

	Trade Name
1	
2	
3	
4	
5	
	Common/Generic Name (Include if no Trade Name)

SECTION F PRIOR RELATED SUBMISSIONS FOR THIS DEVICE OR STUDY

FDA document numbers of all prior related submissions (*regardless of outcome*) or state no prior submission in box 1.

1	2	3
4	5	6
7	8	9
10	11	12

SECTION G PRODUCT CLASSIFICATION – APPLICABLE TO ALL SUBMISSIONS

Product Code(s) (*when applicable*) (*If more than one, please separate with commas.*)

C.F.R. Section (*If applicable*) Classification Panel/Medical Specialty

Device Class
 Class I Class II Class III Unclassified

SECTION H1 REASON FOR APPLICATION – PMA, PDP, OR HDE

<input type="checkbox"/> New Device <input type="checkbox"/> STED <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> HDE Request for Annual Distribution Number (ADN)	<input type="checkbox"/> Change in Design, Component, or Specification: <input type="checkbox"/> Software/Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>Specify below</i>)	<input type="checkbox"/> Location Change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager <input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study
<input type="checkbox"/> Process Change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Vendor/Supplier Change <input type="checkbox"/> Other (<i>Specify below</i>)	<input type="checkbox"/> Labeling Change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> PAS update <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>Specify below</i>)	<input type="checkbox"/> Amendment: <input type="checkbox"/> Withdrawal <input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Address <input type="checkbox"/> Request for Extension <input type="checkbox"/> Response to FDA Correspondence <input type="checkbox"/> Other (<i>Specify below</i>)

Bundle Submission – *If this is selected, list in the spaces below any PMAs in the Bundle.*

1	2	3
4	5	6
7	8	9

SECTION H2

REASON FOR APPLICATION – IDE

<input type="checkbox"/> Original IDE	<input type="checkbox"/> Report: <ul style="list-style-type: none"> <input type="checkbox"/> Adverse Effect <input type="checkbox"/> Final, Study Completed <input type="checkbox"/> Annual Progress <input type="checkbox"/> Interim Progress <input type="checkbox"/> Semiannual Investigator List <input type="checkbox"/> Failure to Obtain Informed Consent <input type="checkbox"/> Compassionate Use Follow-up <input type="checkbox"/> Emergency Use <input type="checkbox"/> Live Case Follow-up <input type="checkbox"/> Completion of Patient Enrollment <input type="checkbox"/> Completion of Patient Follow-up <input type="checkbox"/> Other (<i>Specify below</i>)
<input type="checkbox"/> Supplement: <ul style="list-style-type: none"> <input type="checkbox"/> New Study/New Protocol <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change in Manufacturer <input type="checkbox"/> Change in Sponsor <input type="checkbox"/> Change in Design <input type="checkbox"/> Change in Informed Consent <input type="checkbox"/> Change in Manufacturing <input type="checkbox"/> Change in Protocol <input type="checkbox"/> 5-Day Notice – Device or Manufacturing <input type="checkbox"/> 5-Day Notice – Protocol <input type="checkbox"/> Compassionate Use Request (under an IDE) <input type="checkbox"/> Live Case Request <input type="checkbox"/> Request Deviation from Protocol <input type="checkbox"/> Expansion of Study (Study/Sites) <input type="checkbox"/> Extension of Time to Submit Annual Report or Respond to FDA Letter 	Supplement (<i>Continued</i>) <ul style="list-style-type: none"> <input type="checkbox"/> Request for Waiver <input type="checkbox"/> IRB Certification <input type="checkbox"/> Request for CMS Recategorization <input type="checkbox"/> Study Resumed <input type="checkbox"/> Study Suspension <input type="checkbox"/> Other (<i>Specify below</i>)
<input type="checkbox"/> Amendment to Original IDE: <ul style="list-style-type: none"> <input type="checkbox"/> Amendment Before Final Decision <input type="checkbox"/> Response to Refuse to Accept <input type="checkbox"/> Response to Disapproval <input type="checkbox"/> Response to Approval with Conditions <input type="checkbox"/> Withdrawal <input type="checkbox"/> Other (<i>Specify below</i>) 	<input type="checkbox"/> Amendment to Supplement: <ul style="list-style-type: none"> <input type="checkbox"/> Response to Disapproval <input type="checkbox"/> Response to Approval with Conditions <input type="checkbox"/> Withdrawal <input type="checkbox"/> Amendment Before Final Decision (additional Information) <input type="checkbox"/> Other (<i>Specify below</i>)
<input type="checkbox"/> Amendment to Report: <ul style="list-style-type: none"> <input type="checkbox"/> Response to Deficiency Letter <input type="checkbox"/> Withdrawal <input type="checkbox"/> Amendment Before Final Decision (additional Information) <input type="checkbox"/> Other (<i>Specify below</i>) 	

SECTION H3

REASON FOR SUBMISSION – Q-SUBMISSION

<input type="checkbox"/> Pre-Submission: <ul style="list-style-type: none"> <input type="checkbox"/> Request Face-to-Face Meeting <input type="checkbox"/> Request Teleconference <input type="checkbox"/> Request Email Response <input type="checkbox"/> Submit Meeting Minutes <input type="checkbox"/> Request Meeting Minutes Disagreement T-con 	<input type="checkbox"/> Submission Issue Meeting: <ul style="list-style-type: none"> <input type="checkbox"/> Request Face-to-Face Meeting <input type="checkbox"/> Request Teleconference <input type="checkbox"/> Request Email Response <input type="checkbox"/> Submit Meeting Minutes <input type="checkbox"/> Request Meeting Minutes Disagreement T-con 	<input type="checkbox"/> Additional Information <ul style="list-style-type: none"> <input type="checkbox"/> Change in Legal Entity: <ul style="list-style-type: none"> <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change in Sponsors <input type="checkbox"/> Change in Manufacturer <input type="checkbox"/> Other (<i>Specify below</i>)
<input type="checkbox"/> Agreement Meeting: <ul style="list-style-type: none"> <input type="checkbox"/> Request Face-to-Face Meeting <input type="checkbox"/> Request Teleconference 	<input type="checkbox"/> Determination Meeting: <ul style="list-style-type: none"> <input type="checkbox"/> Request Face-to-Face Meeting <input type="checkbox"/> Request Teleconference 	<input type="checkbox"/> Informational Meeting: <ul style="list-style-type: none"> <input type="checkbox"/> Request Face-to-Face Meeting <input type="checkbox"/> Request Teleconference <input type="checkbox"/> Submit Meeting Minutes <input type="checkbox"/> Request Meeting Minutes Disagreement T-Con
<input type="checkbox"/> Other (<i>Specify</i>): _____		

SECTION H4 REASON FOR SUBMISSION – 510(k)

<input type="checkbox"/> Original <input type="checkbox"/> Withdrawal of Original	<input type="checkbox"/> Amendment Before Final Decision: <input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Withdrawal	<input type="checkbox"/> Supplement: <input type="checkbox"/> Response to Refuse to Accept (RTA) <input type="checkbox"/> Response to Additional Information Request <input type="checkbox"/> Withdrawal
<input type="checkbox"/> Reprocessed SUD		<input type="checkbox"/> Amendment After Final Decision <input type="checkbox"/> Corrective Action
<input type="checkbox"/> Third Party (Complete Section C)		<input type="checkbox"/> STED
<input type="checkbox"/> Other Reason (Specify): _____		

Information on devices to which substantial equivalence is claimed (If known)

	510(k) Number	Trade Name	Submitter	Product Code
Primary Predicate (A)				
Predicate or Reference Device (B)				

To add another Predicate or Reference Device (B) entry row, please click on the button to the right. May be repeated as needed.

Add Device Information

SECTION H5 DE NOVO SUBMISSIONS

Post NSE De Novo: Number of the 510(k) that was NSE'd in the past 30 days: _____
 Withdrawal

SECTION H6 REASON FOR APPLICATION – CLIA

Includes CLIA Parent Document number, CR number, or CW number.

CLIA Categorization Record (CR):
 CLIA Categorization of marketed device (include marketing submission number) _____
 CLIA Categorization of device exempt from premarket review
 Additional information regarding an open CR (include CR number) _____

CLIA Waiver by Application (CW):
 Request for CLIA Waiver by Application for marketed device (include marketing submission number) _____
 Request for Dual 510(k) Clearance and CLIA Waiver by Application (include Pre-submission number) _____
 Response to FDA correspondence
 Additional information regarding an open CW (include CW number) _____

Other Reason (Specify) _____

SECTION I MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

Applicable only to IDEs

Note: Submission of this information does not affect Registration and Listing.

FDA Document Number (if known)

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager/Relabeler
Company/Institution Name			Establishment Registration Number/FEI (if known)	
Street Address			City	
State/Province	ZIP/Postal Code		Country	
Contact 1 Name			Contact 1 Title	
Contact 1 Division Name (if applicable)			Contact 1 Phone Number (including area code)	
Contact 1 Fax Number (including area code)		Contact 1 Email Address		
Contact 2 Name			Contact 2 Title	
Contact 2 Division Name (if applicable)			Contact 2 Phone Number (including area code)	
Contact 2 Fax Number (including area code)		Contact 2 Email Address		
Contact 3 Name			Contact 3 Title	
Contact 3 Division Name (if applicable)			Contact 3 Phone Number (including area code)	
Contact 3 Fax Number (including area code)		Contact 3 Email Address		

To add another set of Section I items, please click on the button to the right. May be repeated as needed.

Add Section I

SECTION J UTILIZATION OF STANDARDS

Note: Please see guidance document titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" for details on the Declaration of Conformity.

How to fill out this section:

Recognition Number: State the FDA recognition number. If the standard is not recognized, write **NR**.

Declaration of Conformity or General Use: Select 'Declaration of Conformity' if including a "Declaration of Conformity to a Recognized Standard" statement. For all other uses, select 'General Use' and indicate if you have made deviations from the Recognized/Non-recognized standard.

Standard: State the Standards Development Organization (SDO), the Designation Number (including year), and the Title.

Location: State the section and/or the page number(s) in the submission where the standard is applied.

Examples

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 <input checked="" type="checkbox"/>	8-185	Declaration of Conformity	If General Use, Deviation?	ASTM F451-08, standard specification for acrylic bone cement.	Section 3, p. 15
2 <input checked="" type="checkbox"/>	3-44	General Use	If General Use, Deviation? Yes	AAMI ANSI BP22:1994 (R) 2011 Blood Pressure Transducers	Section 4, p. 32

Entries for Utilization of Standards

Recognition Number	Declaration of Conformity or General Use	Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 <input type="checkbox"/>	<i>If General Use, Deviation?</i>		

*To add another row for Section J, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)*

SECTION K UTILIZATION OF CDRH GUIDANCE DOCUMENTS

How to fill out this section:

Title: Enter the title of the guidance documents used in the preparation of your premarket submission. CDRH guidance documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>.

Entries for Utilization of CDRH Guidance Documents

Title of Guidance Document
1 <input type="checkbox"/>

*To add another row for Section K, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)*

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 .5 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
PRASStaff@fda.hhs.gov

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