DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved: OMB No. 0910-0120
Expiration Date: Xxxxxxx xx, 201x
See PRA Statement on last page.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(If known)*

SECTION A — TYPE OF SUBMISSION

PMA & PDP

- ☐ Original
- ☐ Modular Submission
- ☐ Amendment
- ☐ Report (annual or PAS)
- ☐ Report Amendment
- ☐ Other:
  - ☐ Premarket Report (reprocessed SUD)
  - ☐ Licensing Agreement

PMA/PDP Supplement

- ☐ 180 day - PAS protocol or labeling change, location change, trade name change
- ☐ 180 day - Design or labeling change
- ☐ Special CBE
- ☐ Panel Track
- ☐ 30-day Notice
- ☐ Real-time Review
- ☐ Amendment to PMA/PDP Supplement

510(k)

- ☐ Original Submission:
  - ☐ Traditional
  - ☐ Special
  - ☐ Abbreviated
  - ☐ 3rd Party Traditional
  - ☐ 3rd Party Special
  - ☐ 3rd Party Abbreviated
  - ☐ Dual Track (Dual 510(k) and CLIA Waiver by Application)
- ☐ Amendment
- ☐ Supplement

CLIA

CLIA Categorization Record (CR)

- ☐ Original
- ☐ Amendment

CLIA Waiver by Application (CW)

- ☐ Original
- ☐ Amendment
- ☐ Supplement

Q-Submission

- ☐ Pre-Submission
- ☐ Informational Meeting
- ☐ Submission Issue Meeting
- ☐ Day 100 Meeting
- ☐ Agreement Meeting
- ☐ Determination Meeting
- ☐ Study Risk Determination
- ☐ Other *(Specify below)*

IDE

- ☐ Original IDE:
  - ☐ Amendment to Original IDE
- ☐ Supplement:
  - ☐ Amendment to Supplement
- ☐ Report:
  - ☐ Amendment to Report

HDE

- ☐ Original Submission
- ☐ Amendment to Original
- ☐ Report
- ☐ Report Amendment
- ☐ HDE Supplement:
  - ☐ 75-day Supplement
  - ☐ 30-day Notice
  - ☐ Special CBE
  - ☐ Amendment to Supplement

Class II Exemption Petition

- ☐ Original Submission
- ☐ Additional Information

De Novo

- ☐ Original:
  - ☐ Direct
  - ☐ Post-NSE
- ☐ Amendment
- ☐ Supplement

Other Submission

- ☐ 513(g)
- ☐ Appeal
- ☐ Other *(Briefly describe submission below)*

Emergency Use Authorization

- ☐ Original
- ☐ Supplement
- ☐ Amendment
- ☐ Report

Pre-Emergency Use Authorization

- ☐ Original
- ☐ Supplement
- ☐ Amendment

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 *(if known)*
Street Address		City
State/Province	ZIP/Postal Code	Country

Contact Name	Contact Title
Division Name *(if applicable)*	Phone Number *(including area code)*
Fax Number *(including area code)*	Contact Email Address

PSC Publishing Services (301) 443-6740 EF

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.

- ☐ Adults Only (greater than 21 years of age)
- ☐ Adults and Pediatrics
- ☐ Neonate/Newborn (birth through 28 days)
- ☐ Infant (from 29 days to 2 years of age)
- ☐ Child (from 2 years to 12 years of age)
- ☐ Adolescent (from 12 years to 18 years of age)
- ☐ Transitional Adolescent A (18 through 21 years of age)
- ☐ Transitional Adolescent B (18 through 21 years of age)
- ☐ Other *(Specify below)*

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

☐ New Device
☐ STED

☐ Post-approval Study Protocol

☐ HDE Request for Annual Distribution Number (ADN)

☐ Change in Design, Component, or Specification:
- ☐ Software/Hardware
- ☐ Color Additive
- ☐ Material
- ☐ Specifications
- ☐ Other *(Specify below)*

☐ Location Change:
- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager

☐ Report Submission:
- ☐ Annual or Periodic
- ☐ Post-approval Study

☐ Process Change:
- ☐ Manufacturing
- ☐ Packaging
- ☐ Sterilization
- ☐ Vendor/Supplier Change
- ☐ Other *(Specify below)*

☐ Labeling Change:
- ☐ Indications
- ☐ Instructions
- ☐ PAS update
- ☐ Performance Characteristics
- ☐ Shelf Life
- ☐ Trade Name
- ☐ Other *(Specify below)*

☐ Amendment:
- ☐ Withdrawal
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Address
- ☐ Request for Extension
- ☐ Response to FDA Correspondence
- ☐ Other *(Specify below)*

☐ 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

☐ Original IDE

☐ Supplement:
- ☐ New Study/New Protocol
- ☐ Change in Correspondent
- ☐ Change in Manufacturer
- ☐ Change in Sponsor
- ☐ Change in Design
- ☐ Change in Informed Consent
- ☐ Change in Manufacturing
- ☐ Change in Protocol
- ☐ 5-Day Notice – Device or Manufacturing
- ☐ 5-Day Notice – Protocol
- ☐ Compassionate Use Request (under an IDE)
- ☐ Live Case Request
- ☐ Request Deviation from Protocol
- ☐ Expansion of Study (Study/Sites)
- ☐ Extension of Time to Submit Annual Report or Respond to FDA Letter

Supplement *(Continued)*
- ☐ Request for Waiver
- ☐ IRB Certification
- ☐ Request for CMS Recategorization
- ☐ Study Resumed
- ☐ Study Suspension
- ☐ Other *(Specify below)*

☐ Report:
- ☐ Adverse Effect
- ☐ Final, Study Completed
- ☐ Annual Progress
- ☐ Interim Progress
- ☐ Semiannual Investigator List
- ☐ Failure to Obtain Informed Consent
- ☐ Compassionate Use Follow-up
- ☐ Emergency Use
- ☐ Live Case Follow-up
- ☐ Completion of Patient Enrollment
- ☐ Completion of Patient Follow-up
- ☐ Other *(Specify below)*

☐ Amendment to Original IDE:
- ☐ Amendment Before Final Decision
- ☐ Response to Refuse to Accept
- ☐ Response to Disapproval
- ☐ Response to Approval with Conditions
- ☐ Withdrawal
- ☐ Other *(Specify below)*

☐ Amendment to Supplement:
- ☐ Response to Disapproval
- ☐ Response to Approval with Conditions
- ☐ Withdrawal
- ☐ Amendment Before Final Decision (additional Information)
- ☐ Other *(Specify below)*

☐ Amendment to Report:
- ☐ Response to Deficiency Letter
- ☐ Withdrawal
- ☐ Amendment Before Final Decision (additional Information)
- ☐ Other *(Specify below)*

SECTION H3 REASON FOR SUBMISSION – Q-SUBMISSION

☐ Pre-Submission:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Request Email Response
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-con

☐ Submission Issue Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Request Email Response
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-con

☐ Additional Information

☐ Change in Legal Entity:
- ☐ Change in Correspondent
- ☐ Change in Sponsors
- ☐ Change in Manufacturer
- ☐ Other *(Specify below)*

☐ Agreement Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference

☐ Determination Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference

☐ Informational Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-Con

☐ Other *(Specify)*: _____

SECTION H4 REASON FOR SUBMISSION – 510(k)

- ☐ Original
- ☐ Withdrawal of Original
- ☐ Amendment Before Final Decision:
  - ☐ Change in Ownership
  - ☐ Change in Correspondent
  - ☐ Withdrawal
- ☐ Amendment After Final Decision
- ☐ Supplement:
  - ☐ Response to Refuse to Accept (RTA)
  - ☐ Response to Additional Information Request
  - ☐ Withdrawal
- ☐ Reprocessed SUD
- ☐ Corrective Action
- ☐ STED
- ☐ Third Party *(Complete Section C)*
- ☐ 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)*

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ 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 X	8-185	Declaration of Conformity	*If General Use,* Deviation?	ASTM F451-08, standard specification for acrylic bone cement.	Section 3, p. 15
2 X	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 X			*If General Use,* Deviation?		

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.)

Add Row/Standard

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 X	

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.)

Add Row/Document

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

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