CDRH Modular Submission Cover Sheet

Information provided by the FDA

M _____	M _____	A _____	S _____
Shell Number	**Module Number**	**Amendment Number**	**Supplement Number**

Type of Submission *Information provided by Sponsor*

Shell ☐ Shell Amendment ☐ Module ☐ Module Amendment ☐ Module Supplement ☐

Submission Information

Date of Submission: _____ Number of Copies: _____

ODE Divisional and Branch: _____ Division Contact:_____

Device - Common Name: _____

Device - Trade Name: _____

Product Code:_____

Company/Institution Name:	Establishment Registration Number:
Division Name (if applicable):	Phone Number (include area code): ( )
Street Address:	Fax Number (include area code): ( )

City:	State/Province:	Country:

Contact Name:

Contact Title:	Contact e-mail Address:

Content of Module *Information provided by Sponsor* - (Check all that Apply)

☐ **AN** Animal Testing	☐ **ES** Electronic Testing	☐ **MT Mechanical Testing**	☐ **RP Reproducibility**
☐ **AL** Analytical Studies (IVD)	☐ **EV** Environmental Testing	☐ **NC Non-clinical Studies**	☐ **SH Shipping Testing**
☐ **BA** Battery Testing	☐ **FW** Firmware	☐ **OM Operators Manual**	☐ **SL Shelf Life/Protocol**
☐ **BB Bibliography**	☐ **GI** General Information	☐ **OP Optical Testing**	☐ **SS Stress**
☐ **BC** Biocompatibility	☐ **HA** Hazard Analysis	☐ **PA Post-approval Studies**	☐ **ST Sterility**
☐ **BT** Bench Testing	☐ **HW** Hardware	☐ **PC Preclinical Studies (IVD)**	☐ **SW Software**
☐ __ **Certification of Conformance**	☐ **IM** Immunology	☐ **PI Packaging**	☐ __ **SS&E Data**
☐ **CH** Chemistry	☐ **LB Labeling**	☐ **PM Post-marketing Studies**	☐ __ **Table of Contents**
☐ **CS** Clinical Studies	☐ **MI Microbiology**	☐ **PS Performance Standards**	☐ **TX Toxicology**
☐ **DD** Device Description	☐ __ **Manufacturing Info.**	☐ **RD Predicted Reliability & Durability**	
☐ **EC** Electromagnetic Compatibility	☐ **MR MRI Compatibility**	☐ **RE Reuse**	☐ **WR Wear**
☐ **EG** Engineering			

☐ **OT Other Include in comments**

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