K101789

I. SUMMARY AND CERTIFICATION

AUG 19 2010

A. 510(k) Summary

Submitter: SterilMed, Inc.

Contact Person: Garrett Ahlborg
11400 73rd Avenue North
Maple Grove, MN 55369
Ph: 763-488-3483
Fax: 763-488-2051

Date Prepared: June 25, 2010

Trade Name: Reprocessed Electrophysiology Diagnostic Catheters

Classification Name: Electrode Recording Catheter or Electrode Recording Probe

Classification Number: Class II, 21 CFR 870.1220

Product Code: NLH

Predicate Devices:	The reprocessed EP diagnostic catheters are substantially equivalent to Irvine Biomedical, Inc. catheters (510(k)'s K060757, K053582, K042775, K010471, K990958, K982232, K961924, and K946333).
Device Description:	SterilMed Reprocessed Irvine Biomedical EP diagnostic catheters consist of a shaft with a handle at the proximal end and some models are considered to be steerable. These catheters have a varying outer diameter (French size) and length. These catheters also feature a number of platinum, radiopaque electrodes with a variety of inter-electrode spacing configurations and curve styles at the distal tip. The distal tip may be steerable and cables connect to the handle and interface between the catheter and an external stimulator and /or an electrophysiological recorder. Note: Only the catheter is the subject of this submission, the external stimulator and /or electrophysiological recorder and any other related equipment are not included in the scope of this submission.
Intended Use:	The reprocessed EP diagnostic catheters are intended for temporary use during electrophysiology studies for intracardiac sensing, recording, cardiac stimulation, and for the electrophysiological mapping and evaluation of cardiac structures and arrhythmias.
Functional and Safety Testing:	Representative samples of reprocessed EP diagnostic catheters were tested to demonstrate appropriate functional characteristics. Process validation testing was performed to validate the cleaning and sterilization procedures as well as device packaging. In addition, the manufacturing process includes visual and validated functional testing of all products produced.
Summary of Non-clinical Tests Conducted:	Specific non-clinical tests performed included: cleaning validation, sterilization validation (ISO 11135, USP <71>), biocompatibility testing (ISO 10993-1), ethylene oxide residual testing (ISO 10993-7), packaging validation (ASTM D4169, ASTM F88, ASTM F1929, ASTM F2096), and shelf life validation (ASTM 1980-99). In addition, validation of functional performance (bench testing) was performed and included the following tests: electrical leakage, torsional strength, flexation fatigue, fluid integrity, joint bond strength, deflection fatigue, catheter stiffness, and tip buckling.
Conclusion:	The reprocessed EP diagnostic catheters are substantially equivalent to the Irvine Biomedical, Inc. electrophysiology diagnostic catheters. This conclusion is based upon the devices' similarities in functional design (principle of operation), materials, indications for use and methods of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SterilMed, Inc.
c/o Mr. Garret Ahlborg
Regulatory Affairs Manager
11400 73rd Avenue North
Maple Grove, MN 55369

AUG 19 2010

Re: K101789
Trade/Device Name: Reprocessed EP Diagnostic Catheter (See Enclosed List)
Regulatory Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: II (two)
Product Code: 74 NLH
Dated: June 25, 2010
Received: June 28, 2010

Dear Mr. Ahlborg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

LIST OF DEVICE MODELS COVERED BY THIS SUBMISSION:

Item	Description	Trade Name	Electrodes	French	Electrode Spacing	Curve Type
81587	1120-7-1(2.5)-SM-AF20	A-Focus II Steerable Atrial	20	7F	1(2.5) mm	20 mm diameter
81589	1114-7-15-SM-AF20	A-Focus II Steerable Atrial	14	7F	1-5-1 mm	20 mm
81591	1114-7-13-SM-AF15	A-Focus II Steerable Atrial	14	7F	1-3mm	15 mm
81594	1110-7-3.5-SM-AF15	A-Focus II Steerable Atrial	10	7F	3.5mm	15 mm
81595	1110-7-5-SM-AF	A-Focus II Steerable Atrial	10	7F	5 mm	20 mm
81596	1110-7-27-SM-AF20	A-Focus II Steerable Atrial	10	7F	2-7mm	20 mm
81597	1110-7-2(11)-SM-AF25	A-Focus II Steerable Atrial	10	7F	2(11) mm	25 mm
81598	1120-7-1(4.5)-SM-AF25	A-Focus II Steerable Atrial	20	7F	1(4.5) mm	25 mm
81599	1110-7-8-SM-AF25	A-Focus II Steerable Atrial	10	7F	8mm	25 mm
81670	1112-5-2-(10)-AF20	A-Focus II Steerable Atrial	12	5F	2(10) mm	25 mm
81671	1114-5-2(9)-AF30	A-Focus II Steerable Atrial	14	5F	2(9) mm	30 mm
81672	1110-5-27-SM-AF20	A-Focus II Steerable Atrial	10	5F	2-7 mm	20 mm
81673	1110-5-5-SM-AF20	A-Focus II Steerable Atrial	10	5F	5mm	20 mm
81674	1110-5-5S-AF20	A-Focus II Steerable Atrial	10	5F	5mm	20 mm
81676	1110-5-3.5-AF15	A-Focus II Steerable Atrial	10	5F	3.5mm	15 mm
81680	1110-5-3.5-SM-AF15	A-Focus II Steerable Atrial	10	5F	3.5mm	15 mm
81503	1104-6-5-L-TE2BE2-BD	Inquiry Bi-Directional	4	6F	5mm	Large 4.1 cm
81504	1110-6-5-M-TE2BE2-BD	Inquiry Bi-Directional	10	6F	5mm	Med 3.2 cm
85931	1924-S	Inquiry Diagnostic Connecting Cables	n/a	n/a	1.5m length	n/a
85953	1910-SA	Inquiry Diagnostic Connecting Cables	n/a	n/a	1.5m length	n/a
85954	1904-SA	Inquiry Diagnostic Connecting Cables	n/a	n/a	1.5m length	n/a
85955	1914-SA	Inquiry Diagnostic Connecting Cables	n/a	n/a	1.5m length	n/a
85930	1910-SA	Inquiry Diagnostic Connecting Cables	n/a	n/a	2.5m length	n/a
80001	1010-6-25-J	Inquiry Fixed Curve	10	6F	2-5-2 mm	Josephson
80002	1010-6-25-C	Inquiry Fixed Curve	10	6F	2-5-2 mm	Coumand
80003	1010-6-28-SC	Inquiry Fixed Curve	10	6F	2-8-2 mm	Special
80051	1010-5-2-J	Inquiry Fixed Curve	10	5F	2MM	Josephson
80052	1010-5-25-J	Inquiry Fixed Curve	10	5F	2-5-2 mm	Josephson
80055	1010-5-25-C	Inquiry Fixed Curve	10	5F	2-5-2 mm	Coumand
80063	1010-5-28-C	Inquiry Fixed Curve	10	5F	2-8-2 mm	Special Curve
80064	1010-5-28-SC(60)	Inquiry Fixed Curve	10	5F	2-8-2 mm	Special Curve
80065	1010-5-25-SC(60)	Inquiry Fixed Curve	10	5F	2-5-2 mm	Special Curve
80116	1010-6-2-J-TE4BE4	Inquiry Fixed Curve	10	6F	2 mm	Josephson
80131	1010-4-5-C	Inquiry Fixed Curve	10	4F	5mm	Cournand
80132	1010-4-5(10)5-J1	Inquiry Fixed Curve	10	4F	2-5-2 mm	Cournand
80133	1010-4-2-J	Inquiry Fixed Curve	10	4F	2 mm	Josephson

80134	1010-4-5-J	Inquiry Fixed Curve	10	4F	5 mm	Josephson
80135	1010-4-25-J	Inquiry Fixed Curve	10	4F	2-5-2 mm	Josephson
80137	1010-4-5(50)-JI	Inquiry Fixed Curve	10	4F	5(50)5 mm	Josephson 1
80138	1010-4-5(10)-JI	Inquiry Fixed Curve	10	4F	5(50)5 mm	Josephson 1
80405	1004-6-25-J	Inquiry Fixed Curve	4	6F	2-5-2 mm	Josephson
80406	1004-6-5-C	Inquiry Fixed Curve	4	6F	5 mm	Josephson
80407	1004-6-2-7	Inquiry Fixed Curve	4	6F	2 mm	Cournand
80408	1004-6-5-J	Inquiry Fixed Curve	4	6F	2-5-2 mm	Cournand
80409	1004-6-5-C	Inquiry Fixed Curve	4	6F	5 mm	Cournand
80411	1004-6-25-D	Inquiry Fixed Curve	4	6F	2-5-2 mm	Domato
80412	1004-6-5-D	Inquiry Fixed Curve	4	6F	5 mm	Domato
80413	1004-6-10-J	Inquiry Fixed Curve	4	6F	10mm	Josephson
80414	1004-6-10-C	Inquiry Fixed Curve	4	6F	10mm	Cournand
80415	1004-6-10-D	Inquiry Fixed Curve	4	6F	10mm	Domato
80451	1004-5-2-J	Inquiry Fixed Curve	4	5F	2mm	Josephson
80452	1004-5-25-J	Inquiry Fixed Curve	4	5F	2-5-2 mm	Josephson
80453	1004-5-5-J	Inquiry Fixed Curve	4	5F	5mm	Josephson
80455	1004-5-25-C	Inquiry Fixed Curve	4	5F	2-5-2 mm	Cournand
80456	1004-5-5-C	Inquiry Fixed Curve	4	5F	5mm	Cournand
80458	1004-5-25-C	Inquiry Fixed Curve	4	5F	2-5-2 mm	Domato
80459	1004-5-5-D	Inquiry Fixed Curve	4	5F	5mm	Domato
80463	1004-5-10-C	Inquiry Fixed Curve	4	5F	10mm	Cournand
80464	1004-4-2-C	Inquiry Fixed Curve	4	4F	2mm	Cournand
80465	1004-4-5-C	Inquiry Fixed Curve	4	4F	5mm	Cournand
80466	1004-4-25-C	Inquiry Fixed Curve	4	4F	2-5-2mm	Cournand
80467	1004-4-2-J	Inquiry Fixed Curve	4	4F	2mm	Josephson
80468	1004-4-5-J	Inquiry Fixed Curve	4	4F	5mm	Josephson
80469	1004-4-25-J	Inquiry Fixed Curve	4	4F	2-5-2mm	Josephson
80484	1004-5-5-J1	Inquiry Fixed Curve	4	5F	5mm	Josephson I
80485	1004-4-5-JI	Inquiry Fixed Curve	4	4F	5mm	Josephson I
80501	1005-6-25-C	Inquiry Fixed Curve	5	6F	2-5-2mm	Cournand
80508	1005-6-25-J	Inquiry Fixed Curve	5	6F	2-5-2mm	Josephson
80535	1004-4-25-JI	Inquiry Fixed Curve	4	4F	2-5-2mm	Josephson I
80536	1004-4-5-D	Inquiry Fixed Curve	4	4F	5mm	Domato
80602	1006-6-25-J	Inquiry Fixed Curve	6	6F	2-5-2mm	Josephson
80603	1006-6-5-J	Inquiry Fixed Curve	6	6F	5mm	Josephson
80604	1006-6-2-C	Inquiry Fixed Curve	6	6F	2mm	Cournand
80606	1006-6-5-C	Inquiry Fixed Curve	6	6F	5mm	Cournand
80803	1008-6-5-J	Inquiry Fixed Curve	8	5F	5mm	Josephson
80804	1008-6-2-C	Inquiry Fixed Curve	8	6F	2mm	Cournand
80806	1008-6-5-D	Inquiry Fixed Curve	8	6F	5mm	Damato
80810	1008-6-5-C	Inquiry Fixed Curve	8	6F	5mm	Cournand
80900	1014-7-3(70)-TE2BE2	Inquiry Fixed Curve	14	7F	3-3-3-3-3-3-70	Cournand
81110	1110-6-17-H	Inquiry H Steerable Atrial	10	6F	1 & 7mm	H
81120	1120-7-17-H	Inquiry H Steerable Atrial	20	7F	1 & 7mm	H
81121	1121-7-17-H-SC	Inquiry H Steerable Atrial	21	7F	1-7-1mm	H-SC

81124	1124-7-271-H	Inquiry H Steerable Atrial	24	7F	2-7-1mm	H
81125	1106-6-27-H	Inquiry H Steerable Atrial	6	6F	2-7-2mm	H
81126	1110-6-291-HL	Inquiry H Steerable Atrial	10	6F	2-9-1mm	HL
81128	1121-7-5-H-UP	Inquiry H Steerable Atrial	21	7F	5mm	H
81130	1120-7-19-HL	Inquiry H Steerable Atrial	20	7F	1 & 9mm	HL
81131	1121-7-19-HL-SC	Inquiry H Steerable Atrial	21	7F	1-9-1mm	HL-SC
81134	1124-7-291-HL	Inquiry H Steerable Atrial	24	7F	2-9-1mm	HL
81136	1120-7-5-HL-UP	Inquiry H Steerable Atrial	20	7F	5mm	HL
81142	1106-6-27-HL	Inquiry H Steerable Atrial	6	6F	2-7-2mm	HL
81150	1124-7-271-H-SCE	Inquiry H Steerable Atrial	24	7F	2-7-1mm	H-SCE
80567	1004-4-5-C(HIS)	Inquiry HIS Fixed	4	4F	5mm	Cournand
80820	1008-5-5-(20)5-C(HIS)	Inquiry HIS Fixed	8	5F	20(5)mm	Cournand
81101	1110-6-2-F	Inquiry Steerable Curves	10	6F	2mm	Med 3.2 cm
81102	1110-6-25-M	Inquiry Steerable Curves	10	6F	2-5-2mm	Med 3.2 cm
81104	1110-6-25-L	Inquiry Steerable Curves	10	6F	2-5-2mm	Large 4.1 cm
81105	1110-6-25-XL	Inquiry Steerable Curves	10	6F	2-5-2mm	X-Large 5.0cm
81106	1110-6-25-F	Inquiry Steerable Curves	10	6F	2-5-2mm	Far Reach
81107	1110-6-5-L	Inquiry Steerable Curves	10	6F	5mm	Large
81108	1110-6-2-L	Inquiry Steerable Curves	10	6F	2mm	Large
81109	1110-6-2-L-TE2BE2	Inquiry Steerable Curves	10	6F	2mm	Large
81171	1110-5-2-M	Inquiry Steerable Curves	10	5F	2mm	Med 3.2 cm
81172	11.10-5-25-M	Inquiry Steerable Curves	10	5F	2-5-2mm	Med 3.2 cm
81174	1110-5-25-L	Inquiry Steerable Curves	10	5F	2-5-2mm	Large 4.1 cm
81176	1110-5-25-L	Inquiry Steerable Curves	10	5F	2-5-2mm	Far Reach
81177	1110-5-5-L	Inquiry Steerable Curves	10	5F	5mm	Large 4.1 cm
81178	1110-5-2-L	Inquiry Steerable Curves	10	5F	2mm	Large 4.1 cm
81179	1110-5-2-E	Inquiry Steerable Curves	10	5F	2mm	Extended Reach
81223	1110-5-2(20)3-XL	Inquiry Steerable Curves	10	5F	2(50)3mm	x-large
81401	1104-6-5-S	Inquiry Steerable Curves	4	6F	5 mm	Small 2.7 cm
81402	1104-6-25-M	Inquiry Steerable Curves	4	6F	2-5-2mm	Medium 3.2
81403	1104-6-5-M	Inquiry Steerable Curves	4	6F	5mm	Medium 3.2
81404	1104-6-25-L	Inquiry Steerable Curves	4	6F	2-5-2mm	Large 4.2 cm
81405	1104-6-5-L	Inquiry Steerable Curves	4	6F	5mm	Large 4.2 cm
81406	1104-6-25-E	Inquiry Steerable Curves	4	6F	2-5-2mm	Extended Reach
81407	1104-6-25-F	Inquiry Steerable Curves	4	6F	2-5-2mm	Far Reach
81412	1104-6-2-E	Inquiry Steerable Curves	4	6F	2mm	Extended Reach
81417	1104-6-5-XL	Inquiry Steerable Curves	4	6F	5mm	X-Large 5.0
81418	1104-6-25-XL	Inquiry Steerable Curves	4	6F	2-5-2mm	X-Large 5.0
81471	1104-5-5-S	Inquiry Steerable Curves	4	5F	5mm	Small 2.7 cm
81472	1104-5-25-M	Inquiry Steerable Curves	4	5F	2-5-2mm	Med 3.2 cm
81473	1104-5-5-M	Inquiry Steerable Curves	4	5F	5mm	Med 3.2 cm
81474	1104-5-25-L	Inquiry Steerable Curves	4	5F	2-5-2mm	Large 4.1 cm
81475	1104-5-5-L	Inquiry Steerable Curves	4	5F	5mm	Large 4.1 cm
81478	1104-5-2-S	Inquiry Steerable Curves	4	5F	2mm	Small 2.7 cm

81479	1104-5-25-S	Inquiry Steerable Curves	4	5F	2-5-2mm	Small 2.7 cm
81511	1105-6-25-M	Inquiry Steerable Curves	6	6F	2-5-2mm	Med 3.2 cm
81520	1110-6-2-XL-TE4BE4	Inquiry Steerable Curves	10	6F	2mm	X-Large 5.0
81524	1110-6-2-L-TE4BE4	Inquiry Steerable Curves	10	6F	2mm	Large 4.1 cm
81530	1110-4-2-M	Inquiry Steerable Curves	10	4F	2mm	Med 3.2 cm
81531	1110-4-25-M	Inquiry Steerable Curves	10	4F	2-5-2mm	Med 3.2 cm
81532	1110-4-025-L	Inquiry Steerable Curves	10	4F	2-5-2mm	Large 4.1 cm
81534	1110-4-5-L	Inquiry Steerable Curves	10	4F	5mm	Large 4.1 cm
81536	1110-4-25-M(80)	Inquiry Steerable Curves	10	4F	2-5-2mm	Med 3.2 cm
81537	1110-4-25-M(SC)(60)	Inquiry Steerable Curves	10	4F	2-5-2mm	Med 3.2 cm
81540	1104-4-25-M	Inquiry Steerable Curves	4	4F	2-5-2mm	Med 3.2 cm
81541	1104-4-2-M	Inquiry Steerable Curves	4	4F	2mm	Med 3.2 cm
81542	1104-4-5-M	Inquiry Steerable Curves	4	4F	5mm	Med 3.2 cm
81543	1104-4-25-L	Inquiry Steerable Curves	4	4F	2-5-2mm	Large 4.1 cm
81545	1104-4-5-L	Inquiry Steerable Curves	4	4F	5mm	Large 4.1 cm
81601	1106-6-5-M	Inquiry Steerable Curves	6	6F	5mm	Med 3.2 cm
81602	1106-6-5-L	Inquiry Steerable Curves	6	6F	5mm	Large 4.1 cm
81603	1106-6-5-E	Inquiry Steerable Curves	6	6F	5mm	Extended Reach
81604	1106-6-5-F	Inquiry Steerable Curves	6	6F	5mm	Far Reach
81605	1106-6-5-XL	Inquiry Steerable Curves	6	6F	5mm	X-Large 5.0
81801	1108-6-2-M	Inquiry Steerable Curves	8	6F	2mm	Med 3.2 cm
81802	1108-6-25-M	Inquiry Steerable Curves	8	6F	2-5-2 mm	Med 3.2 cm
81807	1108-6-2-L	Inquiry Steerable Curves	8	6F	2mm	Large 4.1 cm
81809	1108-6-25-L	Inquiry Steerable Curves	8	6F	2-5-2 mm	Large 4.1 cm
81871	1108-5-2-M	Inquiry Steerable Curves	8	5F	2mm	Med 3.2 cm
81872	1108-5-25-M	Inquiry Steerable Curves	8	5F	2-5-2 mm	Med 3.2 cm
81873	1108-5-5-M	Inquiry Steerable Curves	8	5F	5mm	Med 3.2 cm
81877	1108-5-2-L	Inquiry Steerable Curves	8	5F	2mm	Large 4.1 cm
81879	1108-5-25-L	Inquiry Steerable Curves	8	5F	2-5-2 mm	Large 4.1 cm
81683	1120-7-1(4.5)-SM-OPT25	Optima Steerable Lasso	20	5F	1(4.5)-1(4.5)mm	25-15mm
81659	1120-7-1(4.5)-SM-OPT25-EB	Optima Steerable Lasso	20	7F	1(4.5)-1(4.5)mm	25-15mm
81687	1110-7-10-SM-OPT25	Optima Steerable Lasso	10	7F	10mm	25-15mm
81717	1124-7-1(4.5)(20)(3)-SM-OPT25	Optima Steerable Lasso	24	7F	4(4.5)	25-15mm
81202	1120-7-2-10-XXL	Ten-Ten Duodecapolar	20	7F	2-10mm	XX Large 4.8
81207	1120-7-5-SL	Ten-Ten Duodecapolar	20	7F	5mm	Super Lrg 5.1
81209	1120-7-25-SL	Ten-Ten Duodecapolar	20	7F	2-5mm	Super Lrg 5.1
81211	1120-7-2(20)2(25)2-SL	Ten-Ten Duodecapolar	20	7F	2(20)2(25)2mm	Super Lrg 5.1
81901	1120-7-13-M	Ten-Ten Duodecapolar	20	7F	1-3mm	Med 3.2 cm
81902	1120-7-13-L	Ten-Ten Duodecapolar	20	7F	1-3mm	Large 4.2 cm

Indications for Use

510(k) Number (if known): K101789

Device Name: Reprocessed Electrophysiology Diagnostic Catheters

Indications for Use:

The reprocessed electrophysiology diagnostic catheters are indicated for temporary use during electrophysiology studies for intracardiac sensing, recording, cardiac stimulation, and for the electrophysiological mapping and evaluation of cardiac structures and arrhythmias.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101789