DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 22, 2016

Medline ReNewal
Brandi Panteleon
Director, Quality Assurance/Regulatory Affairs
Medline ReNewal
2747 SW 6th St
Redmond, Oregon 97756

Re: K151617
Trade/Device Name: Medline ReNewal Reprocessed St. Jude Medical Livewire Electrophysiology Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II
Product Code: NLH
Dated: December 17, 2015
Received: December 18, 2015

Dear Brandi Panteleon:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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

4.0 Indications for Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
TBD K151617

Device Name
Medline ReNewal Reprocessed St. Jude Medical Livewire Electrophysiology Catheter

Indications for Use *(Describe)*
The Medline ReNewal Reprocessed St. Jude Medical Livewire Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

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.

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510(k) Summary – K151617

Submitter/ Owner	Medline ReNewal 2747 SW 6th St. Redmond, OR 97756
Contact Names	Brandi Panteleon Director, QA/RA P: 541-923-3310 F: 541-923-3375 E: bpanteleon@medline.com
Date Prepared	June 19, 2015
Device Names	Proprietary Name: Medline ReNewal Reprocessed Livewire Electrophysiology Catheter Common Name: Diagnostic Electrophysiology Catheter, Reprocessed
Classification	Classification: Class II Regulation Number: 870.1220 Product Code: NLH
Predicate Device	K022380 St. Jude Medical Livewire Electrophysiology Catheter
Device Description	Medline ReNewal Reprocessed St. Jude Livewire Electrophysiology Catheters are commonly placed at the high right atrium, right ventricular apex and His bundle, and in the coronary sinus, and are used for electrogram recording and cardiac stimulation during diagnostic electrophysiology studies.
Statement of Intended Use	Medline ReNewal Reprocessed Electrophysiology catheters can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.
Technological Characteristics	The Medline ReNewal Reprocessed Electrophysiology Catheters contain various electrode spacing and a steerable design with a tip that can be shaped into a user-desired curve. The technological characteristics of the proposed devices are substantially equivalent to the predicate devices listed in this submission. The proposed devices are a reprocessed version of the predicate devices. Only Medline ReNewal reprocesses the Medline ReNewal Reprocessed St. Jude Livewire Electrophysiology Catheters. Catheters are reprocessed a maximum of two times. Catheters are marked and taken out of service after the maximum number of cycles is reached.
Performance Testing	The functional characteristics of the subject device have been evaluated and found to be substantially equivalent to the predicate device based on the following tests: • Functional performance studies: ○ simulated use and artificial soiling; ○ bond strength (tensile testing); ○ torsional strength; ○ leakage current; ○ steerable deflection and continuity;

	○ catheter/handle joint flexibility and continuity (flex fatigue); ○ electrode adherence; ○ applied force deflection (tip flexibility); ○ shaft flexibility; ○ tip buckling; ○ direct current resistance; ○ impedance at 5 kHz; and ○ corrosion resistance. • Cleaning: ○ protein, total organic carbon, and endotoxins; ○ visual inspection under magnification; and ○ cleaning performance qualification. • Biocompatibility: ○ cytotoxicity; ○ sensitization; ○ irritation; ○ acute systemic toxicity; ○ pyrogenicity; ○ hemocompatibility (hemolysis, thrombogenicity; and complement activation). • Packaging and shelf life validation; sterilization validation: ○ bioburden testing; and ○ ethylene oxide and ethylene chlorohydrin residuals testing. • Product stability
Conclusion	Based on comparisons of the indications for use, intended use, technological characteristics, and performance data to the predicate devices, Medline ReNewal Reprocessed St. Jude Medical Livewire Electrophysiology Catheters are substantially equivalent to the predicate device.