



Food and Drug Administration
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January 6, 2016

Surgical Instrument Services and Savings Incorporated
Ms. Brandi Panteleon
Acting Director, Quality Assurance and Regulatory Affairs
2747 Southwest 6th Street
Redmond, Oregon 97756

Re: K152313

Trade/Device Name: Medline Renewal Reprocessed Endopath Endoscopic Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: December 8, 2015
Received: December 9, 2015

Dear Ms. 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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Reprocessed Single-Use Device Models Included in Clearance:

Device Model	Device Name	Original Manufacturer
5DCD	Endopath 5 mm Diameter Endoscopic Instruments – Curved Dissector	Ethicon Endo-Surgery
5DCS	Endopath 5 mm Diameter Endoscopic Instruments – Curved Scissors	Ethicon Endo-Surgery

Indications for Use

510(k) Number (if known)
K152313

Device Name
Medline ReNewal Reprocessed Endopath Endoscopic Instruments

Indications for Use (Describe)

Medline ReNewal Reprocessed Endopath 5DCD and 5DCS 5-mm Diameter Endoscopic Instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection and transection of tissue.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

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K152313

5.0 510(k) Summary

Submitter/ Owner	Medline ReNewal 2747 SW 6th St. Redmond, OR 97756
Contact Name	Brandi Panteleon Acting Director, Quality Assurance/Regulatory Affairs P: 541-923-3310 F: 541-923-3375 E: bpanteleon@medline.com
Date Prepared	August 13, 2015
Device Names	Proprietary Name: Reprocessed Medline ReNewal Endopath 5-mm Diameter Endoscopic Instruments
Classification	878: General and plastic surgery devices 21 CFR §878.4400 – electrosurgical cutting and coagulation device and accessories. Class II, product code NUJ
Predicate Device	K984240 Endopath Endoscopic Instruments manufactured by Ethicon Endo-Surgery, Inc.
Device Description	Medline ReNewal Reprocessed Endopath 5DCD and 5DCS 5-mm Diameter Endoscopic Instruments (originally manufactured by Ethicon Endo-Surgery) are cleaned, refurbished, tested, inspected packaged, labeled, and sterilize for an additional clinical use.
Statement of Intended Use	Medline ReNewal Reprocessed Endopath 5DCD and 5DCS 5-mm Diameter Endoscopic Instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection and transection of tissue.
Technological Characteristics	The technological characteristics and the scientific technology of the subject devices are identical to the predicate devices listed in this submission. The proposed devices are a reprocessed version of the predicate devices.
Performance Testing	The functional characteristics of the subject devices have been evaluated and found to be equivalent to the predicate devices based on the following tests: <ul style="list-style-type: none"> • Simulated use; grasping/pulling force; • Cutting effectiveness/functionality; • Device integrity; • Coagulation evaluation; • Cleaning; <ul style="list-style-type: none"> • Protein, carbohydrates, visual inspection (under magnification) • Biocompatibility; <ul style="list-style-type: none"> • Cytotoxicity, sensitization, irritation, acute systemic toxicity and pyrogenicity • Functional performance validation;



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- Electrical safety in accordance with IEC 60601-1;
 - Electrical safety in accordance with IEC 60601-1-2;
 - Electrical safety in accordance with IEC 60601-2-2;
 - Thermal analysis characterization;
 - Sterilization validation; and
 - Product stability.

Conclusion

Based on comparisons of the indications for use, intended use. Technological characteristics and performance data to the predicate devices, Reprocessed Medline ReNewal Endopath 5-mm Diameter Endoscopic Instruments are substantially equivalent to the predicate devices.
