DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Surgical Instrument Service and Savings (dba Medline ReNewal)
Ms. Brandi Panteleon
Director, Quality Assurance and Regulatory Affairs
2747 Southwest 6th Street
Redmond, Oregon 97756

December 16, 2015

Re: K150524
Trade/Device Name: Medline ReNewal Reprocessed Harmonic FOCUS+ Shears without Adaptive Tissue Technology
Regulatory Class: Unclassified
Product Code: NLQ
Dated: December 4, 2015
Received: December 7, 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" (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 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

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

Enclosure

Device Models Subject to Clearance:

Model Number	Device Description	Device Length	Active Blade Length
HAR9FM	Medline ReNewal Reprocessed Harmonic FOCUS+ Shears without Adaptive Tissue Technology	9 cm	16 mm

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)*
K150524

Device Name
Medline ReNewal Reprocessed Harmonic FOCUS+ Shears without Adaptive Tissue Technology

Indications for Use *(Describe)*

Medline ReNewal Reprocessed Harmonic FOCUS+ Shears without Adaptive Tissue Technology is indicated for soft-tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to, or substitute for, electrosurgery, lasers, and steel scalpels in general, otorhinolaryngolic (ear, nose and throat [ENT]), plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open procedures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

(replacement page 25 of 88)

5.0 510(k) Summary

Submitter/ Owner	Medline ReNewal 2747 SW 6th St. Redmond, OR 97756
Contact Names	Brandi Panteleon Director, Regulatory Affairs P: 541-923-3310 F: 541-923-3375 E: bpanteleon@medline.com
Date Prepared	May 5, 2015
Device Names	Proprietary Name: Medline ReNewal Harmonic FOCUS+ Shears without Adaptive Tissue Technology Common Name: scalpel, ultrasonic, reprocessed
Classification	Unclassified/Scalpel, Ultrasonic, Reprocessed Product Code: NLQ
Predicate Device	K133314 – Ethicon Endo-Surgery Harmonic FOCUS Shears + Adaptive Tissue Technology
Reference Devices	K124033 – MEDISISS Reprocessed Ultrasonic Instrument K100597 – Ethicon Endo-Surgery Harmonic FOCUS Shears
Device Description	Medline ReNewal Reprocessed Harmonic FOCUS+ Shears without Adaptive Tissue Technology (originally manufactured by Ethicon Endo-Surgery) are cleaned, refurbished, tested, inspected, packaged, and sterilized for an additional clinical use.
Intended Use	Medline ReNewal Reprocessed Harmonic FOCUS+ Shears without Adaptive Tissue Technology is indicated for soft-tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to, or substitute for, electrosurgery, lasers, and steel scalpels in general, otorhinolaryngolic (ear, nose and throat [ENT]), plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open procedures.

(replacement page 26 of 88)

Technological Characteristics	The technological characteristics and the fundamental scientific technology of the subject device are identical to the predicate and reference devices: • K133314 – Ethicon Endo-Surgery Harmonic FOCUS Shears + Adaptive Tissue Technology; used as the primary predicate to support intended use, technological characteristics, and functional performance specifications; • K124033 – MEDISISS Reprocessed Ultrasonic Instrument; used as a reference predicate to support cleaning, biocompatibility, and product stability of the reprocessed device, and • K100597 – Ethicon Endo-Surgery Harmonic FOCUS Shears; used as a reference predicate to identify design progression of the original device.
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: • simulated use; • grasping/pulling force; • cutting effectiveness/functionality; • drop test; • device integrity; • cutting/coagulation evaluation for a prolonged period of time; • thermal analysis characterization; • tissue sticking; • vessel burst pressure; • electrical safety in accordance with IEC 60601-1; • cleaning; ○ protein, carbohydrates, hemoglobin, and endotoxins; • biocompatibility; ○ sensitization, irritation, and acute systemic toxicity; • performance qualification; • sterilization validation; and • product stability.
Conclusion	Based on the information provided, the Medline ReNewal Reprocessed Harmonic FOCUS+ Shears without Adaptive Tissue Technology are substantially equivalent to the predicate device.