DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 18, 2014

Medline Renewal
Mr. Richard D. Wynkoop
Vice President
Quality Assurance & Regulatory Affairs
2747 SW 6th Street
Redmond, Oregon 97756

Re: K142022
Trade/Device Name: Medline ReNewal Reprocessed Gyrus-Diego Sinus Application Blades
Regulation Number: 21 CFR 874.4140
Regulation Name: Ear, nose, and throat bur
Regulatory Class: Class I
Product Code: NLY
Dated: November 12, 2014
Received: November 17, 2014

Dear Mr. Wynkoop:

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,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

List of models cleared in K142022:

- 7013-8000 Serrated Sinus Application Blade
- 7013-8001 Serrated Sinus Application Blade
- 7013-8002 Smooth, Round Tip Sinus Application Blade
- 7013-8003 Smooth, Square Tip Sinus Application Blade
- 7013-8033 Serrated Sinus Application Blade
- 7013-8034 Turbinate Sinus Application Blade
- 7013-8035 Serrated Sinus Application Blade
- 7013-8100 Aggressive Sinus Application Blade

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Indications for Use

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

510(k) Number *(if known)*
K142022

Device Name
Medline ReNewal Reprocessed Gyrus-Diego Sinus Application Blades

Indications for Use *(Describe)*
Medline ReNewal Reprocessed Gyrus-Diego Sinus Application Blades are designed for use in limited sinus applications involving soft tissue and thin bone such as lamina papyracea.

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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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	Richard D. Wynkoop VP, Quality Assurance & Regulatory Affairs P: 541-923-3310 F: 541-923-3375 E: rwynkoop@medline.com
Date Prepared	December 15, 2014	
Device Names	Proprietary Name: Medline ReNewal Reprocessed Gyrus-Diego Sinus Application Blades Common Name: ear, nose, and throat shaver, reprocessed	
Classification	§ 874.4140 - ear, nose, and throat bur Class I, nonexempt Product Code NLY	
Predicate Device	K020594 Sinus Application Blades of the Diego Powered Dissector and Drill System manufactured by OLYMPUS/Gyrus ACMI.	
Device Description	Medline ReNewal Reprocessed Gyrus-Diego Sinus Application Blades are sterile single use devices that have been cleaned, disinfected, inspected, refurbished, tested, packaged, labeled, and sterilized. The Medline ReNewal Reprocessed Gyrus-Diego Sinus Application Blades are originally manufactured by OLYMPUS/Gyrus ACMI.	
Statement of Intended Use	Medline ReNewal Reprocessed Gyrus-Diego Sinus Application Blades are designed for use in limited sinus applications involving soft tissue and thin bone such as lamina papyracea.	
Technological Characteristics	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.	
Performance Testing	The functional characteristics of the proposed devices have been evaluated and found to be equivalent to the predicate devices after the specified number of reprocessing cycles. Testing included: • biocompatibility testing performed in accordance with ISO 10993-1:2009, • cleaning validation, • product stability, • product performance (bench) tests included: o device integrity, o use and operation using simulated clinical use and artificial test soil, o hub strength,	

	o blade sharpness, o irrigation function, and o outflow function.
Conclusion	Based on comparisons of the indications for use, intended use, technological characteristics, and performance data to the predicate devices, Medline ReNewal Reprocessed Gyrus-Diego Sinus Application Blades are substantially equivalent to the predicate devices.

Table 1: Predicate and Medline ReNewal Reprocessed Gyrus-Diego Sinus Application Blades device comparison chart.

Device Characteristics	Predicate	Proposed	Comparison
	Sinus Application Blades of the Diego Powered Dissector and Drill System	**Medline ReNewal Reprocessed Gyrus-Diego Sinus Application Blades**	**Same device; different manufacturer**
Predicate 510(k)	K020594	TBD	N/A
Product Name	Gyrus-Diego Sinus Application Blades	Reprocessed Gyrus-Diego Sinus Application Blades	N/A
Intended Use	Gyrus Sinus Application Blades are intended to be used with the powered reusable hand piece of the Powered Diego Dissector and Drill System and are designed for use in sinus applications.	Medline ReNewal Reprocessed Gyrus-Diego Sinus Application Blades are intended to be used with the powered reusable hand piece of the Powered Diego Dissector and Drill System and are designed for use in sinus applications.	Same intended use
Indications for Use	Gyrus Sinus Application Blades are designed for use in sinus applications. Sinus applications include ethmoidectomy/ sphenoehtmoidectomy, polypectomy, septoplasty, transsphenoidal procedures, and procedures such as the removal of septal spurs, antrostomy, and endoscopic dacryocystorhinostomy (DCR).	Medline ReNewal Reprocessed Gyrus-Diego Sinus Application Blades are designed for use in limited sinus applications involving soft tissue and thin bone such as lamina papyracea.	Only the sinus application blades indicated for soft tissue and thin bone such as lamina papyracea will be reprocessed by Medline ReNewal. The predicate indications for use is for the whole system, not just the sinus application blades. Thus, the Medline ReNewal Reprocessed Gyrus-Diego Sinus Application Blades have a more focused indications for use than the predicate system.
Configuration	Insertable blades for powered dissector and drill system	Insertable blades for powered dissector and drill system	Same configuration