January 19, 2022

Gyrus ACMI, Inc.
Dolan Mills
Program Manager, Regulatory Affairs
800 West Park Drive
Westborough, Massachusetts 01581

Re: K212650
Trade/Device Name: Celeris, Disposable Sinus Debrider
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, nose, and throat electric or pneumatic surgical drill
Regulatory Class: Class II
Product Code: ERL
Dated: December 17, 2021
Received: December 20, 2021

Dear Dolan Mills:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Shu-Chen Peng
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212650

Device Name
Celeris Disposable Sinus Debrider
Model numbers: DSDPP100, DSD4000BA, DSD4000SA, DSD2000BA, DSD40MMSC

Indications for Use *(Describe)*
The Celeris System (reusable power pack and Disposable Sinus Debrider) is intended for cutting, coagulation, debriding, and removal of thin bone and soft tissue in general ENT and Sinus/Rhinology procedures. Specific procedures and applications would include:

• FESS (Functional Endoscopic Sinus Surgery) – Including Endoscopic approaches for: Polypectomy, Ethmoidectomy, Sphenoidectomy, Maxillary Antrostomy, Uncinectomy, Frontal Sinusotomy
• Turbinate Reduction / Turbinoplasty, including sub-mucosal resection.

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.

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

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K212650
510(k) Summary

General Information

Manufacturer:	Gyrus ACMI, Inc., an Olympus company 9600 Louisiana Ave. North Brooklyn Park, MN 55445 USA Phone: 1-763-416-3000
Establishment Registration Number:	3011050570
510(k) Submitter:	Gyrus ACMI, Inc. 800 West Park Dr. Westborough, MA 01581
Establishment Registration Number:	3003790304
Contact Person:	Dolan Mills Program Manager, Regulatory Affairs
Date Prepared:	Jan 14, 2022

Device Description

Classification Name:	ENT Electric or Pneumatic Surgical Drill
Regulatory Class	Class 2
Regulation Number	21 CFR 874.4250
Review Panel	Ear, Nose, & Throat Panel
Product Code	ERL
Project Name:	Gyrus ACMI DSD - Desoto
Trade Name(s):	Celeris, Disposable Sinus Debrider
Generic/Common Name:	Electrical Surgical Drill / Shaver
Model Numbers:	DSDPP100, DSD4000SA, DSD4000BA, DSD2000BA, DSD40MMSC

Predicate Device

Gyrus ACMI Inc. Diego® Elite: K123429

Device Description and Technological Characteristics

The Gyrus ACMI Disposable Sinus Debrider (DSD) Celeris System is similar in form and function to the Gyrus ACMI blades and handpieces found within the predicate Diego Elite System cleared under K123429, and its predicate PK Diego cleared under K034004.

The Celeris DSD handpiece is a single-use disposable debrider handle and blade permanently combined with a built-in motor that plugs into a reusable power pack that contains a power supply for motor control. The power pack is also part of the subject system. The power supply is able to auto-adapt to any voltage via the universal power cord connection. Motor control requires software on a controller board inside the power pack.

The handpiece incorporates a rotatable blade and attached RF cable for bipolar models. The blades are either standard, bipolar, or malleable. The bipolar function requires a separate electrosurgical generator (not part of this system), connected via a cable. The cutting performance is equivalent to the current Gyrus ACMI predicate models.

A trigger style button on the DSD handle, or analog footswitch (sold separately) connected to the power pack, activates the blade oscillation and a standard electrosurgical unit footswitch (sold separately) powers the bipolar effect for bipolar blades. The electrosurgical generator and footswitch alone will control the RF energy delivery.

A nosecone on the DSD handpiece allows the blade cutting window to rotate left or right. The blades are offered in 2mm and 4mm variants, either straight or malleable, and standard or bipolar. The malleable blade angle is flexible, and the design allows the blade to be bent with the provided bending fixture up to 60˚ at the user's discretion.

A standard suction tube (sold separately) is attached to the DSD handpiece proximal suction port and a clip attaches the tubing to the power cable. The handpiece power cable plugs directly into the power pack. The non-sterile power pack plugs into a standard power outlet and only provides power to the connected DSD handpiece. When the handpiece is activated power is sent to the motor which oscillates a gear which in turn oscillates the inner blade. For bipolar models, the energy lead from the cable is connected directly to the blade and energy is provided by the separate electrosurgical generator footswitch. For bipolar models, insulation around the cutting window limits energy delivery to the surgical site.

Intended Use / Indications

The Celeris System (reusable power pack and Disposable Sinus Debrider) is intended for cutting, coagulation, debriding, and removal of thin bone and soft tissue in general ENT and Sinus/Rhinology procedures. Specific procedures and applications would include:

- FESS (Functional Endoscopic Sinus Surgery) – Including Endoscopic approaches for: Polypectomy, Ethmoidectomy, Sphenoidectomy, Maxillary Antrostomy, Uncinectomy, Frontal Sinusotomy
- Turbinate Reduction / Turbinoplasty, including sub-mucosal resection.

Compliance to Standards

The following standards were used during the design and testing of the DSD:

IEC 60601-1: 2005
IEC 60601-1-2: 2014
IEC 60601-2-2: 2017
ISO 10993-1: 2018
ISO 10993-5: 2009
ISO 10993-7: 2008
ISO 10993-10: 2010
ISO 11135: 2014
ISO 11607-1: 2019
ISO 11737-2: 2019
ISO 15223-1: 2016
IEC 62304: 2015
ASTM F88/F88M – 2016
ASTM F1886: 2016
ASTM D4169-14: 2016

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971. Design verification sample sizes and tests were identified and performed as a result of risk analysis assessment.

Summary of Performance Testing

The following non-clinical, preclinical tests and usability studies were conducted:

Non-Clinical / Preclinical Performance

Evidence of safety and effectiveness was obtained from two primary areas:

1) non-clinical (electrical, mechanical, functional, stability) performance testing
2) preclinical (bench tissue, simulated use) evaluations and testing

The bipolar device thermal performance has been tested per FDA guidance document, "FDA Guidance for Industry and FDA Staff, Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery", Mar 2020.

The power pack has been tested per FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", issued on May 11, 2005.

Electrical safety and EMC compatibility: Basic safety and performance testing was performed in accordance with IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-2.

Mechanical and Functional: Verification and comparison bench studies were conducted to evaluate the mechanical and functional performance as compared to the predicate.

Stability: Representative samples were subjected to accelerated aging to confirm that the device maintains functionality and continues to meet specifications over time. The results of the accelerated age testing demonstrate that the device will be stable for the stated shelf-life. In addition, real time age testing will confirm the results of the accelerated age testing. Representative samples were also subjected to distribution testing.

Preclinical: Evidence obtained from preclinical bench tissue (ex vivo) and simulated use studies demonstrate that the DSD performs substantially equivalent to the predicate devices in relevant aspects associated with usability, cutting, coagulation, and removal of tissue.

Bench tissue – evaluated ex vivo using bovine tissue:

- Thermal margin
- Thermal impact
- Visual comparison of coagulation
- Microscopic measurement of thermal margin and impact

Software: Device software development and validation were completed per the level of concern and guidance.

Biocompatibility testing: The disposable handpieces are classified in accordance with ISO 10993-1, as an External Communication Device, Tissue/Bone/Dentin, for limited exposure (<24 hours.). ISO 10993-1 and FDA guidelines recommend that these

devices have supporting data for cytotoxicity, sensitization, irritation, and acute systemic toxicity. Full GLP biocompatibility testing to ISO 10993-1 is on file for these devices.

No animal or clinical testing was conducted. The use of the device type has been documented in published literature and indicates safe and effective use for the target procedures and expected patient populations.

Performance testing demonstrated that the device is as safe, as effective, and performs as well as or better than the predicate devices.

Material

The composition of the DSD is similar to the predicate devices. The handle and power pack is not patient-contacting. Patient contacting components are limited to the shaver blade portion up to the nosecone.

Patient contacting materials are primarily plastics and stainless steel.

Sterilization and Shelf Life Discussion

The disposable handpieces are provided sterile, single-use. The devices are sterilized with ETO, using a validated cycle to provide a sterility assurance level of 10^{-6}.

The Shelf Life period for the device was determined via testing and through an analysis of the shelf-life stability of the materials used in the design of the device, as well as an analysis of the packaging materials and processes used with other Gyrus ACMI devices. Shelf-life studies are on file to support the labeled shelf life.

The reusable power pack is provided non-sterile.

Substantial Equivalence

The DSD bipolar models deliver high frequency electrosurgical energy to coagulate tissue in a similar manner as the predicate RF devices.

The DSD cuts and removes tissue in the same manner as the predicate device. The DSD inner blade oscillates at a high rate of speed and as tissue is pulled into the cutting window via suction it is resected and removed. The oscillating portion of the DSD blade is driven by an electric motor inside the handle portion of the device that incorporates a gear transmission to provide the desired range of speeds and torque. The speed is limited by the motor within the handle. The hollow inner blade is attached to a suction supply to facilitate removal of tissue and fluid from the surgical site.

The power pack provides power to the DSD handpiece motor for blade rotation only. The power pack provides power in a similar manner as the predicate console, but focuses on power delivery only.

Predicate comparison table to outline differences and similarities between the subject and predicate devices		
Description	**Subject Device DSD**	**Predicate Device (K123429)**
Intended Use	Cutting, coagulation, debriding, and removal of thin bone and soft tissue in general ENT and Sinus/Rhinology procedures.	Cutting, coagulation, drilling, debriding, and removal of bone and soft and hard tissue in general ENT and Sinus/Rhinology, Nasopharyngeal / Laryngology, and Head & Neck procedures.
Prescription/over-the-counter use	Rx Only	Rx Only
Size(s)	OD: 2mm, 4mm Working Length: 3.9 to 4.3 in.	OD of similar blades: 2 to 4 mm Working Length of similar blades: 4.3 to 5 in
Method of dissection	Conventional rotating cutting blade combined with RF energy hemostasis for specific models	Conventional rotating cutting blade combined with RF energy hemostasis for specific models

Conclusion

The performance of the DSD was compared against performance requirements and the predicate systems listed above. Performance requirements were based on the predicate systems. Testing demonstrated that the performance requirements were met, and that the subject device exhibited comparable performance characteristics to the predicate. Any differences have been validated and demonstrate that the technological features do not raise new questions of safety and efficacy.

In summary, the Gyrus ACMI Cleris DSD is substantially equivalent to the predicate devices and does not raise different questions of safety and effectiveness.