DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 10, 2016

Gyrus Acmi, Inc.
Mr. Dolan Mills
Sr. Specialist, Regulatory Affairs
136 Turnpike Road
Southborough, MA 01772

Re: K152744
Trade/Device Name: Diego Elite Drill
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: May 11, 2016
Received: May 12, 2016

Dear Mr. 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. 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,

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

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)*

K152744

Device Name
Diego Elite Drill

Indications for Use *(Describe)*

The Diego Elite Drill is intended for cutting, drilling, and removal of bone, and soft and hard tissue in general ENT, and Otoneurologic procedures when used in conjunction with the Diego Elite console.

Specific procedures would include Mastoid/Neurotology (Mastoidectomy / Mastoidotomy) and Stapes 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)*

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510(k) Summary of Safety and Effectiveness
Gyrus ACMI, Inc.
Diego Elite Drill

General Information

Manufacturer and 510(k) Submitter:	Gyrus ACMI, Inc., an Olympus company 136 Turnpike Road Southborough, MA 01772-2104 Phone: 1-800-262-3540 Fax: 1-901-373-0260
Establishment Registration Number:	3003790304
Manufacturing Site:	2925 Appling Road Bartlett , TN 38113 Phone: 1-800-262-3540 Fax: 1-901-373-0260
Establishment Registration Number:	1037007
Contact Person:	Dolan Mills Senior Specialist, Regulatory Affairs
Date Prepared:	September 22, 2015

Device Description

Classification Name: ENT Electric or Pneumatic Surgical Drill

Drill System 21 CFR 874.4250 Ear, Nose, Throat ERL	Bur, Ear, Nose & Throat 21 CFR 874.4140 Ear, Nose & Throat EQJ	Tray, Surgical Instrument 21 CFR 878.4800 General & Plastic Surgery FSM

Regulatory Class	Class 2
Regulation Number	21 CFR 874.4250
Review Panel	Ear, Nose, & Throat Panel
Product Code	ERL
Project Name:	Diego Elite Drill (12-002), High Speed Drill
Trade Name(s):	Diego Elite Drill

Generic/Common Name: Electrical Surgical Drill / Shaver Burs, Instrument Tray

Predicate Devices

Gyrus ACMI Diego® RF Powered Dissector & Drill System: K034004

Reference Predicates:
Medtronic Midas Rex: K081277
Gyrus ACMI Diego Elite System: K123429

The Gyrus ACMI predicate has not been subject to a design-related recall.

Product Description

The Diego Elite Drill is similar to the drills associated with the predicate Diego® RF Powered Dissector and Drill System cleared under K034004. The Diego Elite Drill is the next generation drill and it is functionally equivalent to the predicate Gyrus ACMI product and other predicates.

The proposed Drill and accessories are to be used only in conjunction with the Diego Elite system (K123429) for Otologic procedures. The Diego Elite system original submission did not include an Otologic drill, and the predicate (K034004) is not compatible with the Diego Elite system.

Accessories include straight and angled attachments, an irrigation clip, various burrs, an irrigation tubeset, a cleaning kit, and a cleaning / sterilization tray. The drill base plugs into the existing Diego Elite console and is activated by the existing Diego Elite footswitch. The drill base and the straight and angled attachments, and irrigation clip are provided non-sterile and are reusable. The burrs and tubeset are provided sterile and are single-use. The cleaning kit is provided non-sterile and is single-use.

Technological Characteristics

The Drill system is used in the same general way as the predicate RF Diego drills (K034004) and Diego Elite system handpieces (K123429). A reusable drill base connects to the existing Diego Elite console, is recognized by a unique Diego Elite Drill software version, and differentiated from other possible Diego Elite handpiece options. A reusable tip guard, 1 of 5 interchangeable attachments, is connected to the drill; each tip is detected by the drill hardware/software based on its intended use (Mastoid vs. Stapes), and default performance settings (speed, irrigation) are then displayed by the console on the graphical user interface. A disposable burr is then loaded into the drill/guard and locked in to place for use. The total assembly creates a variable speed drill.

A new sterile disposable tubeset delivers irrigation via the existing Diego Elite console pump to the operative site through either a guard-attachable reusable clip or a separate suction / irrigation instrument (sold separately). The new tubeset also provides suction capabilities and is compatible with standard OR suction and the existing Diego Elite Suction Module (K123429). The existing Diego Elite footswitch connects to the console and is used to start and stop the drill operation.

Material

The Diego Elite Drill uses the same patient-contacting materials that are utilized in the predicate devices (K123429, K034004), as well as other legally marketed devices manufactured by Gyrus ACMI.

The patient contacting items are classified in accordance with ISO 10993-1, as an external communicating, tissue/bone/dentin device for limited exposure (<24hrs.). ISO10993-1 and FDA Blue Book memo #G95-1 guidelines recommend that these direct patient contact parts have supporting data for cytotoxicity, sensitization and irritation. Full biocompatibility testing (Cytotoxicity, sensitization, and irritation) to ISO10993-1 for the device category for any material differences was completed and is available for patient contacting materials.

The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Based on the material assessment, patient contacting materials were evaluated as comparable to the predicate or tested in accordance with ISO 10993-1, with passing results.

Intended Use / Indications

The Diego Elite Drill is intended for cutting, drilling, and removal of bone, and soft and hard tissue in general ENT, and Otoneurologic procedures when used in conjunction with the Diego Elite console.

Specific procedures would include Mastoid/Neurotology (Mastoidectomy / Mastoidotomy) and Stapes procedures.

Compliance to Standards

The design of the Diego Elite Drill complies with the following standards:

IEC 60601-1, 2005

ISO 10993-1 (2009), 5 (2009), 7 (2008), 10 (2010), Biological Evaluation of Medical Devices
ISO 14971:2012, Risk Analysis
ISO 15223-1:2012, Medical Devices - Symbols to be used
ISO 17665-1:2006, Sterilization of Health Care Products, Moist Heat
ISO 11135:2014, Sterilization of Health Care Products, EO Validation
ISO 11138: 2006, Sterilization of health care products: Biological Indicators
ISO 11607-1:2006, Packaging for Terminally Sterilized Medical Devices
ISO 11607-2:2006, Packaging for Terminally Sterilized Medical Devices
ISO 11737-1:2006, Sterilization of Medical Devices – Microbiological Methods
ISO 11737-2:2009, Sterilization of Medical Devices – Microbiological Methods

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

Electrical safety

Electrical safety testing was conducted on the device. The device complies with the applicable clauses of IEC 60601-1.

Summary of Sterilization and Shelf Life Discussion

The Drill base and drill components are provided non-sterile and are reusable. The console and footswitch are to be wiped down with cleaning / disinfecting wipes after use. The drill is not in the fluid or suction pathway, and any contamination it receives will be through indirect means from handling and as the disposables are removed. The drill is to be cleaned and reprocessed according to the validated procedure provided in the instruction manual.

The burrs and tubeset are provided sterile for single-use. They are sterilized using Ethylene Oxide, using a cycle validated in accordance with ISO 11135 to provide a sterility assurance level of 10^{-6}.

The Shelf Life period for the disposable items was determined through an analysis of the shelf-life stability of the materials used in the design of the devices, as well as an analysis of the packaging materials and processes used with other Gyrus ACMI devices. Accelerated shelf-life studies were conducted to support an initial one year shelf life, with real time testing in process to confirm an initial one year expiration date. Additional studies (accelerated and real time) are planned to support a five–year expiration date in the future.

Summary of Performance Testing

Performance tests were executed to ensure that the system functioned as intended and met design specifications. The following non-clinical and 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, biocompatibility, stability) performance testing
2) preclinical (simulated use) evaluations and testing

Non-clinical: Basic safety and performance testing was performed in accordance with IEC standards. In addition, verification and comparison bench studies were conducted to evaluate the mechanical and functional performance. Testing included: tip vibration, noise, torque strength, endurance, force testing, reliability, leak testing, ship testing, baseline performance testing, age testing, joint strength, environmental conditioning, durability, and other applicable tests.

Stability: Representative sterile samples were subjected to accelerated aging to confirm that the disposable devices maintain functionality and continue 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 environmental conditioning and ship testing.

Preclinical: Evidence obtained from preclinical simulated use studies demonstrate that the system performs substantially equivalent to the predicate device in relevant aspects associated with usability, cutting, drilling, and removal of tissue. For simulated use testing, the selected test medium (PHACON temporal bone analog) was confirmed to be appropriate for testing based on surgeon input. Testing included:

- Usability aspects such as device setup
- Overall design confidence
- Ergonomics and Control
- Performance

The simulated use testing established substantial equivalence with the predicate device for the intended use based on an assessment of non-clinical performance data, as per 807.92(b). The simulated use testing included feedback from five ENT surgeons using a PHACON temporal bone simulator for simulation of mastoidectomy / mastoidotomy and stapedectomy procedures, and a feasibility DVS study with ten ENT surgeons in which cadaver heads were used in a controlled cadaver lab to perform mastoid and middle ear procedures. The surgeons were asked a series of

questions related to the procedures being simulated and in comparison to the predicate device.

The simulated use testing results were considered passing according to defined acceptance criteria in relation to the expectations of the user for the device type (average score of less than (but not equal to) 2.5 must be achieved for each of the three test sections (Set-up, Ergonomics, Performance)) tested across the surgeon evaluation base. Score options: 1 – Exceeds Expectations; 2 – Meets Expectations; 3 – Nearly Meets Expectations; 4 –Does Not Meet Expectations. The subject device scores were as follows:

- Set-up: 1.7
- Ergonomics: 2.0
- Performance: 2.0

The feasibility DVS study results were considered passing according to our acceptance criteria in relation to the expectations of the user for the device type (average score of less than (but not equal to) 2.3 must be achieved for each of the sections (Set-up, Ergonomics, Performance)) tested across the surgeon evaluation base. The individual survey responses show that in total all procedures were performed satisfactorily with the new device. Score options: 1 - Exceeds Expectations; 2 - Meets Expectations; 3 - Does not Meet Expectations. The subject device scores were as follows:

- Set-up: 1.6
- Ergonomics: 1.7
- Performance: 1.5

Testing demonstrated that the device performs substantially equivalent to the main predicate device in relation to the stated indications, and is as safe and effective, and performs as well as or better than the legally marketed predicate.

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

Substantial Equivalence

The Diego Elite Drill utilizes the same console to cut, drill, and remove tissue as that used in the Diego Elite System cleared under K123429.

The Diego Elite Drill operates as a drill in a similar manner as the predicate drills and burrs found in the currently marketed Diego® RF Dissector and Drill System cleared under K034004. The Diego Elite Drill disposable tubeset and burrs are similar to the predicate devices physically and in their methods of operation. The tubeset continues

to be bifurcated, offering saline irrigation to the surgical site, and suction away from the surgical site.

The Diego Elite Drill uses the same patient-contacting materials in similar quantities that are utilized in the predicate devices, as well as other legally marketed devices manufactured by Gyrus ACMI.

Conclusion

The performance of the Diego Elite Drill was compared against the known performance characteristics of the predicate device. Testing demonstrated that the performance requirements were met, and that the Diego Elite Drill exhibited comparable performance characteristics to the predicate.

In summary, the Diego Elite Drill is substantially equivalent to the predicate device and presents no new questions of safety or efficacy.