510(k) Summary of Safety and Effectiveness
Gyrus ACMI, Inc.
DTAD

AUG 30 2012

General Information

Manufacturer:	Gyrus ENT, L.L.C. (subsidiary of Gyrus ACMI, Inc.) 2925 Appling Road Bartlett , TN 38113 Phone: 1-800-262-3540 Fax: 1-901-373-0237
Establishment Registration Number:	1037007
510(k) Submitter:	Gyrus ACMI, Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	3003790304
Contact Person:	Dolan Mills, RAC Specialist, Regulatory Affairs
Date Prepared:	June 6, 2012

Device Description

Classification Name:	Electrosurgical Cutting & Coagulation Device and Accessories, ENT Electric or Pneumatic Surgical Drill Class 2 21 CFR 878.4400 GEI General and Plastic Surgery Panel 21 CFR 874.4250 ERL Ear, Nose, Throat
Project Name:	Gyrus ACMI DTAD

Trade Name(s):	Disposable Tonsil and Adenoid Device (DTAD)
Generic/Common Name:	Electrical Surgical Drill / Shaver or Electrosurgical cutting and coagulation device and accessories

Predicate Devices

Gyrus ACMI Inc. Diego® RF Powered Dissector & Drill System:	K034004
Covidien / ValleyLab Suction Coagulator:	K091223
Bovie SEER:	K082568
Peak TnA Plasmablade:	K083415

Device Description and Technological Characteristics

The DTAD (Disposable Tonsil and Adenoid Device) is a disposable microdebrider blade with a built-in motor that will plug into the users electrosurgical generator. The sole energy application mode is Monopolar coagulation. The monopolar use will require a return electrode for the generator. The cutting performance is the same as the current Gyrus ACMI Diego® tonsil and adenoid blades cleared under K034004, with the addition of monopolar coagulation. The monopolar effect is completely dependent upon the generator used and its settings, which is the same as the other monopolar predicates.

The device will be a single-use battery operated microdebrider with monopolar capability. A button will activate the blade oscillation and the standard OR electrosurgical unit footswitch will power the monopolar effect. A nosecone will allow the tip to rotate 90° left or right. The blade will be provided at a 40° bend for adenoids with the capability of being reduced to 15° for tonsillectomies. The blade angle is flexible, and the design allows the blade to be bent between 0° and 50°.

The microdebrider device will include a monopolar cable that connects to a separate standard operating room electrosurgical generator. A standard suction tube will be attached to the suction port and a clip will attach the tubing to the cable. Two batteries, provided with a three year shelf life from the manufacturer, will be provided in the DTAD cable to power the blade oscillation. The battery leads connect internally to the PCB in the housing which connects to the oscillation switch and motor. When the handpiece button is pressed, power is sent to the motor which oscillates a gear which in turn oscillates the inner blade gear at approximately 3500 rpm. The monopolar lead from the cable is connected directly to the outer blade and is powered by the electrosurgical generator footswitch.

For user convenience the package will also include a disposable stylet for declogging if needed. The stylet is the same as the one provided in the current Diego® tubeset

package (K034004). The device packaging is similar to the predicate Diego® blades and disposables, and the devices are not labeled as non-pyrogenic.

Material

The DTAD uses patient-contacting materials that are utilized in the predicate devices, as well as other legally marketed devices manufactured by Gyrus ACMI.

The composition of the DTAD is similar to the devices within the previously cleared predicate, Diego® RF Powered Dissector and Drill System, K034004. The handle and RF cable are not patient-contacting materials, and therefore no biocompatibility testing is warranted for those materials. The composition of the patient contacting shaver blade portion is similar to the devices cleared under K034004. The silicone material used as an RF insulator is the same material used in the disposable Gyrus ACMI Plasmacision devices tied to K041285. These devices are used in a similar manner, for the same procedures, manufactured in the same value stream, and are subjected to the same EtO sterilization cycle and process as the DTAD.

The DTAD is 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 is available for the predicate devices containing the same patient contacting materials in similar quantities.

Since Gyrus ACMI does currently utilize the patient contacting materials in other devices with the same intended use no biocompatibility testing is required.

Intended Use / Indications

The DTAD is intended for cutting, coagulation, and removal of tissue in general ENT procedures.

Specific indications include: Tonsillectomy and Adenoidectomy.

Compliance to Standards

The following standards were used during the design and validation of the DTAD:

IEC 60601-1: 2005
IEC 60601-2-2: 2009
ISO 10993-1: 2009
ISO 10993-7: 2008

ISO 11135-1: 2007
ISO 11607-1: 2006
ISO 11607-2: 2006
ISO 15223-1: 2008
ASTM F88 – 09
ASTM F1886-98: 2004

The risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verification tests were identified and performed as a result of risk analysis assessment.

Summary of Sterilization and Shelf Life Discussion

The DTAD will be shipped sterile, for single use only. Each device is sterilized using Ethylene Oxide, using an over-kill cycle validated in accordance with ISO 11135 to provide a sterility assurance level of 10^{-6}. The maximum allowable levels of residues of ethylene oxide, and ethylene chlorohydrin are established. The residual levels are less than those specified in ISO 10993-7.

The product will be released with a one year shelf life, which will later be extended to 3 years after functional accelerated age testing is complete. The Shelf Life period for the DTAD was determined through an analysis of the shelf-life stability of the materials used in the design and packaging of the DTAD, which are the same as those used in the predicate Diego® devices, as well as an analysis of the packaging materials and processes used with other Gyrus ACMI devices. Accelerated shelf-life functionality 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. Functional shelf-life is also dependent upon the useful life of the batteries. Additional functionality studies (accelerated and real time) are in process to support a three–year expiration date in the future.

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, animal) evaluations and testing

Non-clinical: Basic safety and performance testing was performed in accordance with IEC 60601-1 and IEC 60601-2-2. In addition, verification and comparison bench studies were conducted to evaluate the mechanical and functional performance. Specifically, test results in the following areas were provided: functionality, RF

isolation, tip vibration, fluid ingress, battery and blade endurance, cable and connector pull force, monopolar effect, strain relief strength, suction and clog performance, blade flex capability, ability of the cutting edge to resist damage, blade torque, generator compatibility, and operational temperature.

Stability: Representative samples were subjected to accelerated and real time ageing to confirm that the device maintains functionality and continues to meet their 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 ship testing.

Preclinical: Evidence obtained from preclinical bench tissue (ex vivo) and animal (in vivo) studies demonstrate that the DTAD 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

Animal – evaluated in vivo using porcine models:
- Cut, coagulation, and suction
- Ergonomics
- Usability aspects such as device setup, tip rotation, and tip malleability
- Overall design confidence

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

No clinical testing was conducted. The use of Electrosurgical Cutting and Coagulation Devices / Microdebriders has been documented in published literature and indicates safe and effective use for the target procedures and patient populations.

Substantial Equivalence to Predicates

The DTAD utilizes features incorporated into the following legally marketed predicate devices:
The DTAD utilizes high frequency electrosurgical energy to cut and coagulate tissue in a similar manner as the predicate devices.

With the exception of monopolar capability and the built-in battery powered motor, the DTAD cuts and removes tissue in the same manner as the predicate Diego® RF

Dissector and Drill System. The DTAD blade offers monopolar coagulation at the cutting tip only when connected to a monopolar electrosurgical generator. The DTAD blade consists of a rotating inner member with a serrated tip within a stationary outer tube with a cutting window at the tip. The DTAD inner blade has a double helix laser cut that allows the inner blade to be flexible. The outer is spiral cut under an annealed aluminum tube and shrink tubing that allows the blade to be bent between 0° and 50°. The DTAD inner blade oscillates at a high rate of speed and as tissue is pulled into the cutting window it is resected and removed. The oscillating portion of the DTAD 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 Covidien / Valleylab suction monopolar coagulators are intended for general and ENT surgical procedures where the coagulation of tissue and suction of fluids are desired. The Bovie resection device is intended for cutting and monopolar coagulation of soft tissue using radiofrequency. The Peak Plasmablade TnA Tonsil and Adenoid Tissue Dissection device is intended to be used for the cutting and coagulation of soft tissue during otolaryngology (ENT) surgery including adenoidectomy and tonsillectomy.

Conclusion:

The cutting and coagulation performance of the DTAD was compared against performance requirements and the predicate systems listed above. Testing demonstrated that the performance requirements were met, and that the Gyrus ACMI DTAD exhibited comparable performance characteristics to the predicates.

In summary, the Gyrus ACMI DTAD is substantially equivalent to the predicate devices and presents no new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Gyrus ACMI, Incorporated
% Mr. Dolan Mills, RAC
Specialist, Regulatory Affairs
136 Turnpike Road
Southborough, Massachusetts 01772

AUG 30 2012

Re: K121678
Trade/Device Name: DTAD
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, nose, and throat electric or pneumatic surgical drill
Regulatory Class: II
Product Code: ERL
Dated: August 17, 2012
Received: August 20, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Erin Keith

for Mark Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K121678

Device Name: DTAD

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Prescription Use: __ X __ (Per 21 CFR 801.109) AND/OR Over-the-Counter Use: _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K121678