

K123429

Olympus EPS
Gyrus ACMI, Inc.

Traditional 510(k) Notification
November 2012

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

APR 5 2013

General Information

Manufacturer: Gyrus ENT, L.L.C. (a subsidiary of
Gyrus ACMI, Inc., an Olympus
company)
2925 Appling Road
Bartlett, TN 38113
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Establishment Registration Number: 1037007

510(k) Submitter: Gyrus ACMI, Inc.
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Establishment Registration Number: 3003790304

Contact Person: Dolan Mills
Specialist, Regulatory Affairs

Date Prepared: November 6, 2012

Device Description

Classification Name: ENT Electric or Pneumatic Surgical Drill
Electrosurgical Cutting & Coagulation
Device and Accessories
Class 2

Electrosurgical System 21 CFR 878.4400 General and Plastic Surgery Panel GEI	Drill System 21 CFR 874.4250 Ear, Nose, Throat ERL	Suction Pump 21 CFR 878.4780 General and Plastic Surgery Panel JCX
Stereotaxic Instrument 21 CFR 882.4560 Neurology HAW	Bur, Ear, Nose & Throat 21 CFR 874.4140 Ear, Nose & Throat EQJ	Tray, Surgical Instrument 21 CFR 878.4800 General & Plastic Surgery FSM

Project Name: EPS, PKD2 System / Bullitt (09-016)

Trade Name(s): DIEGO ELITE

Generic/Common Name: Electrical Surgical Drill / Shaver or
Electrosurgical cutting and coagulation
device and accessories, Suction Pump,
Stereotaxic Instrument, Burs, Instrument
Tray

Predicate Devices

Gyrus ACMI Diego® RF Powered Dissector & Drill System:	K034004
Gyrus ACMI Diego® Starlink with IGS	K030343
Covidien ValleyLab Force FX	K944602
Gyrus ACMI DTAD	K121678
Olympus KV-5 Powered Suction Pump	K011725

Product Description

The DIEGO ELITE system is the second generation of the RF Diego® system cleared under K034004. The second generation system offers many improvements over the previous system. The DIEGO ELITE includes a power console with touchscreen, footswitch, reusable handpiece, image guided surgery compatibility, an optional powered suction pump, single use disposable accessories and interchangeable burrs / blades and electrosurgical blades. This second generation device adds monopolar capability, disposable sensing technology, improved blades, improved fluid pathway, a more durable reusable handpiece, a premium tubeset with a declog feature and IGS connector, and a powered suction pump that is an optional accessory that can be used to replace the standard facility suction.

Technological Characteristics

The DIEGO ELITE console is a reusable, non-sterile electrosurgical generator and electrical drill system that features monopolar and bipolar cutting and coagulation modes. The maximum output power is 40 W. The console controls operational and performance aspects of the reusable motor module (MDU) handpiece and the suction module.

The front side of the console features a touch screen interface that displays the connection status of accessories. It is also used to show and modify the output settings, such as mode, output power, speed, and irrigation. The front panel has a socket for the MDU, a socket for a neutral electrode, and a socket for the footswitch. The front of the console has a power switch. The console recognizes which

accessories and peripherals are connected and displays default settings and any needed warning indicators. After default settings are loaded, the user may adjust settings as desired. The touch screen also has a menu button that controls various functions and settings.

The side panel offers a peristaltic irrigation pump and irrigant sensing section. The irrigation line is loaded through an air bubble sensor section and then through the irrigation pump. The sensing section identifies when the irrigation line is empty and displays a warning on the touch screen.

The rear panel offers a channel and clamping mechanism to load the console onto a standard IV pole. The rear panel also contains the mains disconnect, grounding post, connection socket for the optional powered suction pump, service port, and back panel labeling. Ventilation holes are in the rear and bottom panel.

The DIEGO ELITE includes an optional suction module that connects to the main controller and can replace the standard facility suction system. The suction system can only be used with the main console.

Application Modes:

Microdebrider only:

- Variable or Constant Speed – selected by user
- Rotation of inner blade – Oscillate, Forward

Monopolar Coagulation:

- Crest Factor (CF): 4.3
 - CF is a description of the waveform
- 390kHz damped sinusoid, every 36 kHz

Bipolar Coagulation:

- Crest Factor (CF): 2.1 at rated load
 - CF is a description of the waveform
- Carrier Frequency: 470 KHz

The DIEGO ELITE handpiece consists of the non-sterile reusable MDU (reusable portion of the handpiece), the sterile disposable blade / burr, and the sterile disposable suction tube connector. The entire fluid pathway is contained in the disposable sections. All electrosurgical leads are contained within the MDU and the monopolar and bipolar disposable blades. The MDU is connected to the console for control, the irrigation tube line is connected through the pump and then the irrigant source. The suction tube is connected to either the facility standard suction, or the optional powered suction pump via a fluid collection canister. The monopolar or bipolar effect is limited to the disposable blade tip, and activation is controlled by the surgeon by pressing a coag button on the top of the blade nosecone.

The system footswitch connects to the console and is used to control microdebridement only. The footswitch also offers a toggle switch on either side of the pedal that can toggle the shaver blade cutting window open or closed when the blade is stopped.

The system blades and burrs are offered in similar working lengths and geometries as the predicate Gyrus ACMI Diego® system, and they include a capacitor that is used to determine the disposable “family” to which it belongs and establish the proper default settings and features that go along with that family.

Image Guided Surgery (IGS) instrumentation / array allows the blades and burrs to be tracked in real time in the surgical field. IGS compatibility is accomplished by moving the connector from the predicate Diego® Starlink handpiece to the top of the premium tubeset connector. This allows for the elimination of an additional handpiece for IGS. The IGS connector (boss) and assembled MDU handpiece is functionally equivalent to the predicate Starlink handpiece, and it will continue to accept the BrainLab AG IGS equipment.

Material

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

The DIEGO ELITE 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 was completed and is available for patient contacting materials.

Based on the material assessment, patient contacting materials were tested in accordance with ISO 10993-1, and results are considered passing. Test results are available in section 12.

Intended Use / Indications

The system, including Image Guided Surgery compatibility, and optional Suction console, is intended for cutting, coagulation, drilling, debriding, and removal of bone, and soft and hard tissue in general ENT, Sinus / Rhinology, Nasopharyngeal / Laryngology, and Head & Neck procedures.

Specific procedures and applications would include:

Sinus / Rhinology:

- FESS (Functional Endoscopic Sinus Surgery)
 - Including Endoscopic approaches to: Polypectomy, Ethmoidectomy, Sphenoidectomy, Maxillary Antrostomy, Uncinectomy, Frontal Sinusotomy
- Septal Spur removal
- Endoscopic DCR
- Trans-sphenoidal procedures specifically to create access through the sinuses to the Pituitary, Skull Base, and CSF leak repair
- Turbinate Reduction / Turbinoplasty
 - Including sub mucosal resection

Nasopharyngeal / Laryngeal:

- Adenoidectomy / Tonsillectomy
- Laryngeal procedures for Recurrent respiratory papilloma, Lesion de-bulking, Polypectomy

Head & Neck:

- Soft tissue shaving

Compliance to Voluntary Standards

The design of the DIEGO ELITE complies with the following standards:

For pro-code GEI - FDA Recognized Consensus Standards: IEC 60601-2-2

Additional voluntary standards:

IEC 60601-1, IEC 60601-1-2

ISO 10079-1:2009, Medical suction equipment - Part 1: Electrically powered suction equipment

ISO 10993-1, 5, 7, 10, Biological Evaluation of Medical Devices

ISO 14971:2007, Risk Analysis

ISO 15223-1:2007 + amd1:2008, Medical Devices - Symbols to be used

ISO 17664: 2004, Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices.

ISO 17665-1:2006, Sterilization of Health Care Products, Moist Heat

ISO 11135-1:2007, Sterilization of Health Care Products, EO Validation

ISO 11138-2: 2006, Sterilization of health care products: Biological Indicators

ISO 11607-1:2009, 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

ASTM F1980-07 - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

ASTM F2097-10 – Flexible Primary packaging

ASTM F1886-09/F1886M-09 – Standard test method for determining integrity of seals

ASTM F1929-98 (2004) – Standard test method for detecting seal leaks with dye penetration

ASTM F88/F88M-09 – Standard test method for seal strength of flexible barrier materials

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

The blades and burrs, and tubesets are provided sterile for single-use. They are sterilized using Ethylene Oxide, using a cycle validated in accordance with ISO 11135-1 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 (bench tissue, cadaver, 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. Testing included: tip vibration, torque strength, endurance, dynamic seal integrity, force testing, reliability, leak testing, ship testing, baseline performance testing, age testing, joint strength, environmental conditioning, durability, aspiration, RF isolation, and many other applicable tests.

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 environmental conditioning and ship testing.

Preclinical: Evidence obtained from preclinical bench tissue (ex vivo) and animal (in vivo) studies demonstrate that the system performs substantially equivalent to the predicate devices in relevant aspects associated with usability, cutting, coagulation, and removal of tissue. For simulated use and bench testing, the selected tissue medium was confirmed to be appropriate for testing based on surgeon input. Sample impedance levels were also investigated and confirmed as appropriate.

Bench tissue – evaluated ex vivo using bovine tissue:

- Thermal margin
- Thermal impact
- Visual comparison of coagulation

Cadaver – evaluated in vivo:

- Cut, coagulation, tissue removal, and suction
- Ergonomics
- Usability aspects such as device setup, tip rotation, and tip malleability
- Overall design confidence

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 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 expected patient populations.

Substantial Equivalence

The DIEGO ELITE utilizes the same bipolar electrosurgical energy to cut and coagulate tissue as that used in the predicate Diego® RF Dissector and Drill System cleared under K034004.

The DIEGO ELITE utilizes similar monopolar electrosurgical energy to cut and coagulate tissue as that used in the predicate ValleyLab Force FX electrosurgical units, and the monopolar disposables operate in a similar manner as the monopolar ValleyLab disposables and the monopolar Gyrus ACMI DTAD device.

The DIEGO ELITE operates as a microdebrider in a similar manner as the predicate burrs and blades found in the currently marketed Diego® RF Dissector and Drill System cleared under K034004. The DIEGO ELITE disposable tubesets, burrs and blades 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 burrs and blades continue to operate as a rotating tube within a tube. The blades have a cutting tip and hollow inner member for resected tissue and fluid to travel through.

The DIEGO ELITE offers IGS compatibility in a similar manner as the Diego® Starlink handpiece cleared under K030343, and it is functionally equivalent with regard to IGS compatibility. The proposed premium tubeset provides a stable base and connector for the IGS equipment to connect to for tip tracking in a similar manner to the Starlink handpiece.

The DIEGO ELITE optional suction pump console operates in a similar manner to the predicate Olympus KV-5 powered suction pump.

The DIEGO ELITE uses similar 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 was compared against the known performance characteristics of the predicate devices. Testing demonstrated that the performance requirements were met, and that the DIEGO ELITE exhibited comparable performance characteristics to the predicates.

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



April 5, 2013

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

Gyrus ACMI, Incorporated
% Mr. Dolan Mills
Specialist, Regulatory Affairs
136 Turnpike Road
Southborough, MA 01722-2104

Re: K123429

Trade/Device Name: DIEGO ELITE
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, nose, and throat electric or pneumatic surgical drill
Regulatory Class: Class II
Product Code: GEI
Dated: February 15, 2013
Received: February 19, 2013

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 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>. 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,

Eric A. Mann

for Malvina Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose
and Throat Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

K123429

Olympus EPS
Gyrus ACMI, Inc.

Traditional 510(k) Notification
November 2012

Indications for Use

510(k) Number: K123429

Device Name: DIEGO ELITE

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- Turbinate Reduction / Turbinoplasty
 - Including sub mucosal resection

Nasopharyngeal / Laryngeal:

- Adenoidectomy / Tonsillectomy
- Laryngeal procedures for Recurrent respiratory papilloma, Lesion de-bulking, Polypectomy

Head & Neck:

- Soft tissue shaving

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)

Vasant G.
Malshet

Digitally signed by Vasant G. Malshet
DN: c=US, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
cn=Vasant G. Malshet,
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Date: 2013.03.19 12:04:47 -04'00'