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## 510(k) Summary of Safety and Effectiveness
## Gyrus ACMI, Inc.
## PK ®Diego® System

### General Information

| | |
|---|---|
| Manufacturer: | Gyrus ENT, L.L.C. (subsidiary of Gyrus ACMI, Inc.)<br>2925 Appling Road<br>Bartlett , TN 38113 |
| Establishment Registration Number: | 1037007 |
| 510(k) Submitter: | Gyrus ACMI, Inc.<br>136 Turnpike Rd.<br>Southborough, MA 01772-2104 |
| Establishment Registration Number: | 3003790304 |
| Contact Person: | Graham A. L. Baillie, MS<br>Senior Regulatory Specialist |
| Date Prepared: | October 2008 |

### Device Description

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|---|---|
| Classification Name: | Electrosurgical Cutting & Coagulation Device and Accessories<br>Class 2<br>21 CFR 878.4400<br>General and Plastic Surgery Panel |
| Project Name: | Gyrus ACMI PK® Diego® System |
| Trade Name(s): | Bipolar Coagulation Device, electrical debriders, drill handpiece, cutting blades and burs, electrical surgical shaver, |
| Generic/Common Name: | Electrosurgical cutting and coagulation device and accessories |

K 083013

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## Predicate Devices

| | |
|---|---|
| Diego RF Powered Dissector & Drill System: | K034004 |
| Endius Bipolar Sheath: | K012488 |
| XPS (MDS) StraightShot Microdebrider System: | K973499 |

## Intended Uses

The PK® Diego® System is intended for cutting, coagulation and removal of bone and tissue in general ENT, Head & Neck, Otoneurologic and various spinal surgical procedures.

## Product Description

The PK Diego System is identical to the device cleared under K034004. The system includes the same power console, footswitch, reusable handpiece and various single use, interchangeable burs and bipolar blades. The sole purpose of this submission is to expand the existing indications to include various spinal surgical procedures.

## Technological Characteristics and Substantial Equivalence

The PK Diego System utilizes features incorporated into the following legally marketed predicate devices:

The PK Diego System 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 PK Diego powered handpiece, burs and bipolar blades connect to the same electrosurgical generator/console, as the predicate and currently marketed Diego RF Dissector and Drill System cleared under K034004. The Diego bipolar blades are dimensionally similar to the predicate XPS (MDS) StraightShot Microdebrider System cleared under K973499, having similar blade shaft and tip diameters.

Like the predicate XPS (MDS) StraightShot Microdebrider System (K973499) and the predicate Endius Bipolar Sheath cleared under K012488, the proposed PK Diego System includes an indication for various spinal surgical procedures.

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

**Continued... Technological Characteristics and Substantial Equivalence**

The bipolar cutting and coagulation performance of the PK Diego System was compared against the known tissue debrider performance characteristics of the predicate XPS (MDS) StraightShot Microdebrider System and the tissue coagulation performance of the predicate Endius Bipolar Sheath. Testing demonstrated that the performance requirements were met, and that the PK Diego System exhibited comparable performance characteristics to both predicates.

In summary, the PK Diego System 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
9200 Corporate Boulevard
Rockville MD 20850

Gyrus ACMI, Inc.
% Mr. Graham A.L. Baillie
Sr. Regulatory Specialist
136 Turnpike Road
Southborough, Massachusetts 01772

DEC 0 9 2008

Re: K083013
Trade/Device Name: Gyrus ENT PK® Diego® Powered Dissector
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 8, 2008
Received: October 9, 2008

Dear Mr. Baillie:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number: 083013**

**Device Name: Gyrus ENT PK® Diego® Powered Dissector**

**Indications for Use:**

The Diego PK System is intended for cutting, coagulation and removal of bone and tissue in general ENT, Head & Neck, Otoneurologic and various spinal surgical procedures.

Prescription Use: __X__ AND/OR Over-the-Counter Use: _____
(Per 21 CFR 801.109) (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 General, Restorative, and Neurological Devices**

**510(k) Number** K083013