MAY - 2 2003

510(k) Summary

Submitter's Name: Submitter's Address: Submitter's Telephone Number:	Gyrus ENT LLC 2925 Appling Road, Bartlett, TN 38133 901.373.0200
Contact Person:	Gregory Sredin
Date Summary Prepared:	January 31, 2003
Proprietary Name:	Diego™ Powered Dissector Handpiece with Starlink™ Image Guided Adapter Mounting Interface
Common Name:	Instrument, Stereotaxic
Classification Name:	Instrument, Stereotaxic
Classification	Class II
Classification Panel:	Neurology
Device Product Code	HAW

Subject Device Description

The Diego Powered Dissector and Drill System Handpiece, cleared under 510(k) K020594, has been modified to accept the BrainLAB VectorVision (K003589) and Kolibri (K014256) Image-Guided Surgery System Instrument Adapter that will allow the Dissector blades and burs to be tracked in real time in the surgical field.

Applicable 510(k)'s

Manufacturer	Submission Name	FDA Clearance
BrainLAB AG	Kolibri IGS System	K014256
BrainLAB AG	Vectorvision2 IGS System	K003589

Subject Device Intended Use

The intended use of the Diego Powered Dissector and Drill System equipped with an image guided surgery system is the cutting and removal of bone and tissue in general ENT, Head & Neck, and otoneurologic procedures.

Sinus applications would embody:

- ethmoidectomy/sphenoethmoidectomy

- polypectomy
- septoplasty and
- procedures such as
  - antrostomy
  - endoscopic DCR
  - frontal sinus drill-out
  - frontal sinus trephination and irrigation
  - septal spurs removal
  - trans-spehnoidal procedures

Nasopharyngeal/laryngeal procedures would comprise:

- adenoidectomy
- laryngeal lesion de-bulking
- laryngeal polypectomy
- tracheal procedures
- tonsillectomy

Head & Neck procedures would encompass:

- soft tissue shaving
- rhinoplasty (narrowing of the bony vault and revision of the bony pyramid)
- removal of fatty (adipose) tissue (lipodebridement) in the maxillary and mandibular regions of the face
- acoustic neuroma removal

Otology procedures would include:

- mastoidectomy
- mastoidotomy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2003

Mr. Gregory Sredin
Senior Regulatory Affairs Specialist
Gyrus ENT LLC
2925 Appling Road
Bartlett, Tennessee 38133

Re: K030343
Trade/Device Name: Diego™ Powered Dissector Handpiece with Starlink™ Image Guided Adapter Mounting Interface
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: January 21, 2003
Received: February 3, 2003

Dear Mr. Sredin:

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 Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Food and Drug Administration **January 31, 2003**
510(k) Notification – Gyrus ENT Image-Guided Diego™ Powered Dissector & Drill System Modified Handpiece

510(k) Number: K030343
Device Name: Diego™ Powered Dissector and Drill System Handpiece with Image Guided Surgery System Interface.

Indications for Use:

The intended use of the Diego Powered Dissector and Drill System is the cutting and removal of bone and tissue in general ENT, Head & Neck, and otoneurologic procedures.

Sinus applications would embody:

- ethmoidectomy/sphenoethmoidectomy
- polypectomy
- septoplasty and
- procedures such as
- antrostomy
- endoscopic DCR
- frontal sinus drill-out
- frontal sinus trephination and irrigation
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- soft tissue shaving
- rhinoplasty (narrowing of the bony vault and revision of the bony pyramid)
- removal of fatty (adipose) tissue (lipodebridement) in the maxillary and mandibular regions of the face
- acoustic neuroma removal

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030343

Prescription Use X OR Over-the-Counter ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)