NOV 17 2003

K024286

H: 510(k) Summary of Safety and Effectiveness

Page 1 of 2

Page 1

December 18, 2002

Company: Gyrus Medical, Inc.
6655Wedgwood Road
Maple Grove, MN
Tel. No. (763) 416-3000
FAX. No. (763) 416-3070

Contact: Mark Jensen
VP Regulatory Affairs / Quality Assurance

Common/Usual Name: Electrosurgical Instruments

Classification Name: Electrosurgical Cutting and Coagulation Device And Accessories (21 CFR 878.4400)

Proprietary Name: Gyrus OPEN FORCEPS

The device is a Class II medical device. The Gyrus OPEN FORCEPS is a modification to the predicate device cleared under K000496. The Open Forceps is similar in construction and in component materials when compared to the predicate device. The indications for use are similar to the predicate devices cleared under K981916 and K010010. The device consists of grasping jaws connected to a handle. The handle has finger loops integrated into it to allow the physician to easily manipulate the device for electrosurgical coagulation including the sealing of vessels. The overall length of the device is nine (9) inches. The device will be available in three distinct jaw configurations. The intended use of the device is to electrosurgically coagulate tissue and the sealing of vessels up to 7mm during the performance of open general surgical procedures. The energy source, Bipolar Electrosurgical Energy, is the same energy type as used for the predicate devices. The forceps jaws are electrically isolated from each other enabling one jaw to act as a return electrode, eliminating the need for a return pad. Preclinical laboratory data and bench test data provide verification that the device is safe and effective and conforms to its Intended Use.

In conclusion, as the design, materials of construction, function and intended use of the Gyrus OPEN FORCEPS is similar to that of the predicate devices currently cleared, Gyrus Medical Inc. believes that no new issues of safety and effectiveness are raised and that the submitted device is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2003

Ms. Mercedes P. Bayani
Director Regulatory and Clinical Affairs
Gyrus Medical, Inc.
6655 Wedgwood Road, Suite 105
Maple Grove, Minnesota 55311-3602

Re: K024286
Trade/Device Name: Gyrus Open Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 19, 2003
Received: September 23, 2003

Dear Ms. Bayani:

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. 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 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

510(k) Number (if known): K024286
Device Name: Gyrus Open Forceps

Indications for Use:

Electrosurgical coagulation, mechanical grasping and dissection of tissue, and sealing of vessels up to 7mm, during the performance of open general surgical procedures.

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

Concurence of CDRH, Office of Device Evaulation (ODE)
(Optional Format 3-10-98)

(Posted July 1, 1998)

Prescription Use ✓ OR Over-the-Counter ___
(Per 21 CFR 801.109)

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

510(k) Number K024286