

XIII. 510(K) SUMMARY

K990628

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1. Name Of Device

Trade name: Gyrus Endourology System
 Common name: Electrosurgical Generator System
 Classification name: Endoscopic Electrosurgical Unit and Accessories
 (21 CFR 876.4300)

2. Equivalence

<u>Device</u>	<u>Premarket Notification</u>
Scuba (Gynecare Versapoint™) System	K962482
Scuba (Gynecare Versapoint™) System G-VAP Electrode	K982738
Gyrus Hysteroscopic Resectoscope	K982771
Erbe ERBOTOM ICC 350	K933002
COMEG Urological Electrosurgical Equipment	K971881

3. Device Description

The Gyrus Endourology System is comprised of four key components: the Electrode, the Connector Cable, an Axipolar Resectoscope and an electrosurgical generator called the Controller. The Connector Cable connects the Controller to the Electrode. The Electrode is provided in a variety of models, ranging in size from 5 Fr. to 24 Fr. A system specific Resectoscope is provided for use with one of the Electrode models. Other Electrode models are available for use with available cystoscopes with a 5Fr or larger operating channel. The Electrode is supplied sterile and intended for single patient use. The Connector Cable is designed for a number of sterilizations and the Resectoscope for repeat sterilizations using steam autoclaving methods. The Controller is an electronic radio frequency generator.

The Gyrus Endourology System is bipolar, incorporating a return electrode as a part of the electrode tip. This means that a return pad is not required for system operation. The return energy in a bipolar device with an integral return electrode does not penetrate the tissue as in a monopolar device. In a monopolar device, the energy passes through the patient's body to reach the return pad.

4. Indicated Use

The Gyrus Endourology System is a radio frequency bipolar electrosurgical device system intended for use in urological surgical procedures involving the ablation or removal of soft tissue and where associated hemostasis is required. The specific urological indications where the system can be used are in transurethral prostatectomy (TURP) for benign prostatic hypertrophy, transurethral incision of the prostate (TUIP) or bladder neck, resection of bladder tumors and in cystodiathermy.

Several manufacturers have marketed equivalent monopolar electrosurgical generators, electrodes and accessories in the USA since the 1950's.

Equivalent monopolar and bipolar electrosurgery devices have been cleared via 510(k), such as those manufactured by Erbe (K933002) and COMEG (K971881). These devices have been demonstrated to be safe and effective in removing tissue during urological surgery.

5. Technological Characteristics

The technological characteristics of the Gyrus Endourology System are the same as those of the Scuba (Gynecare Versapoint™) Electrosurgery System, Electrodes (K962482, K982738) and its dedicated Resectoscope and accessories (K982771). The devices are substantially equivalent in terms of design, materials, principle of operation, product specifications and sterilization.

6. Summary

By virtue of design, materials, function and indicated use, the Gyrus Endourology System is substantially equivalent to similar devices currently marketed in the USA.

7. Regulatory Contact

Please direct any questions regarding this submission to:

David Kay
Director, Regulatory Affairs & Quality Assurance

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St Mellons
Cardiff
CF3 0LT
United Kingdom

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JUN 29 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David Kay
Director, Regulatory Affairs and Quality Assurance
Gyrus Medical LTD.
Fortran Road
St. Mellons
Cardiff CF3 OLT
United Kingdom

Re: K990628
Gyrus Endourology System
Dated: April 12, 1999
Received: April 15, 1999
Regulatory Class: II
21 CFR §876.1500/Procodes: 78 FJL; 78 FDC
21 CFR §876.4300/Procodes: 78 FAS; 78 KNS

Dear Mr. Kay:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990628

Device Name: **Gyrus Endourology System**

Indications for use:

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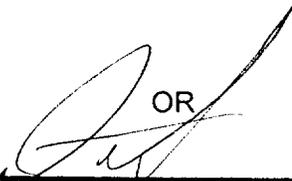
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K990628/501