

DEC 27 1999

SECTION 9

510(k) SUMMARY

1. Name Of Device

Trade name: Gyrus Endourology System: Axipolar Resectoscope Electrode
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>
Gyrus Axipolar Resectoscope Electrode	K990628

3. Device Description

The Axipolar Resectoscope Electrode devices described in this 510(k) are sterile, disposable electrodes designed for use with the Gyrus Endourology System.

4. Indicated Use

The Gyrus Endourology System is 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.

5. Safety & Performance

This submission is a Special 510(k): Device Modification as described in FDA's guidance document entitled "The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), Gyrus has provided certification of compliance to 21 CFR 820.30 design Control requirements, and Risk Analysis procedures.

6. Summary

By virtue of design, materials, function and indicated use, the Gyrus Endourology System Axipolar Resectoscope Electrode 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
Gyrus Medical Limited, Fortran Road, St Mellons, Cardiff, CF3 0LT, UK
Tel: +44 (029) 20 776300 Fax: +44 (029) 20 776301



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David Kay
Director, Regulatory Affairs and Quality Assurance
Gyrus Medical Limited
Fortran Road
St. Mellons
Cardiff CF3 0LT
UNITED KINGDOM

Re: K994166
Gyrus Endourology Electrosurgical System:
Axipolar Resectoscope Electrode
Dated: December 3, 1999
Received: December 9, 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): K994166

Device Name: Gyrus Axipolar Resectoscope Electrode

Indications for Use:

The Gyrus Endourology System, when used with a Gyrus Axipolar Resectoscope Electrode, 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.

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

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 K994166