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K982771

SECTION 7

510(k) Summary of Safety and Effectiveness

Statement

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug, and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

MODIFIED DEVICE NAME: Gyrus Hysteroscopic Resectoscope

PREDICATE DEVICE NAME: COMEG Endoscopy Resectoscope and Karl Storz Hysteroscopic Resectoscope Models 27040/27050.

Device Description

The Gyrus Hysteroscopic Resectoscope that we intend to market employs an electrode specific resectoscope-working element. All other sheaths etc., are standard COMEG components. A "Quick Connection" feature is used to attach the working element to the sheath.

Endoscopic electrosurgical instruments and accessories are described under "Endoscope and Accessories" in 21 CFR 876.1500, and Hysteroscopes are described in 21 CFR 884.1690.

The Hysteroscopic Resectoscope is intended to enable the viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

The surgeon performs the examination through the cervical canal. The working elements are the devices that house and control various electrodes and lasers used to remove cut, coagulate, and transect tissue. The surgeon controls the back and forth movement of the electrode, using finger controls. The working elements also house a telescope for visualization. Current is transmitted to the electrode through a high frequency cable.

These devices are composed of stainless steel, stainless steel chrome plated, plastic and brass chrome plated parts.

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510(k) Summary of Safety and Effectiveness, Continued

Intended Use	The Gyrus Hysteroscopic Resectoscope is intended to enable the viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures. The surgical applications include tissue cutting, removal, and dissection as required or encountered in gynecologic hysteroscopic electrosurgical procedures for the treatment of intrauterine myomas, polyps, adhesions, and septa.
Indications Statement	The Gyrus Hysteroscopic Resectoscope is used to permit the direct viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.
Technological characteristics	The modified device has the same technological characteristics as the predicate devices. The form, fit and function is similar.
Performance Data	Pre-clinical as well as bench top testing has been performed to verify that the product meets the performance requirements described. This substantiates the efficacy of the resectoscope for the hysteroscopic usage.
Conclusion	Based upon the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the predicate devices under the Federal Food, Drug, Cosmetic Act.
Contact	David Kay Director of Regulatory Affairs and Quality Assurance Gyrus Medical Ltd. Fortran Road St. Mellons Cardiff, CF3 0LT United Kingdom
Date	August 4, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 1999

David Kay
Director, Regulatory Affairs & Quality Assurance
Gyrus Medical
Fortran Road
St. Mellons
Cardiff CF3 OLT
UNITED KINGDOM

Re: K982771
Gyrus Axipoler™ Hysteroscopic Resectoscope
Dated: November 23, 1998
Received: November 25, 1998
Regulatory Class: II
21 CFR 884.1690/Procode: 85 HIH

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

INDICATIONS FOR USE

510(k) Number (if known): K982771

Device Name: Gyrus Hysteroscopic Resectoscope

Indications for Use: Used to permit direct viewing and access to the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures. As used with the Gynecare Versapoint System, the indications for use include:

Excision of intrauterine myomas
Excision of intrauterine polyps
Lysis of intrauterine adhesions
Incision of uterine septa

(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 Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982771/S001

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)