K092571

510(k) Summary of Safety and Effectiveness
Gyrus ACMI Incorporated
Gyrus ACMI Inc. BiCoag Hemostasis Probe

General Information

OCT 2 0 2010

Manufacturer:	Gyrus ACMI Incorporated 136 Turnpike Rd. Southborough, MA 01772-2104
Contact Person:	Lorraine Calzetta
Date Prepared:	August 19, 2009

Device Description

Classification Name:	Endoscopic electrosurgical unit and accessories (21CFR 876.4300) Class II Gastroenterology/Urology
Trade Name:	Gyrus ACMI Inc. BiCoag Hemostasis Probe
Generic/Common Name:	Endoscopic electrosurgical accessories.

Predicate Device

Biosearch Hemostatic probe cleared under K912129

Everest Hemostatic Bipolar Probe cleared under K892895

Bard Biprobe cleared under K912601

Intended Uses

The Gyrus ACMI Inc. BiCoag Hemostasis Probe is intended for coagulation of active bleeding lesions in the upper or lower gastrointestinal tract during endoscopic procedures. The device also can be used for irrigation.

Device Description

The BiCoag Hemostasis Probe is intended to be used for coagulation of active bleeding lesions in the upper or lower gastrointestinal tract when used with a bipolar high frequency generator. It contains a central irrigation port. The probe is to be available in 10 Fr and 7 Fr (3.3mm and 2.3mm respectively) outer diameter configurations to allow its use through a minimum 3.7mm and 2.8mm endoscope working channel, respectively.

Technological Characteristics and Substantial Equivalence

The Gyrus ACMI Inc. BiCoag Hemostasis Probe, as described in this submission, is substantially equivalent to the predicates in intended use, materials, principles of operation and fundamental scientific technology.

Summary of Safety and Effectiveness

The Gyrus ACMI Inc. BiCoag Hemostasis Probe, as described in this submission, is substantially equivalent to the predicates in intended use, materials, principles of operation and fundamental scientific technology and raises no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Gyrus ACMI Incorporated
% Ms. Lorraine Calzetta
136 Turnpike Road
Southborough, Massachusetts 01772

OCT 2 0 2010

Re: K092571
Trade/Device Name: Gyrus ACMI Inc. BiCoag Hemostasis Probe
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: KNS
Dated: October 14, 2010
Received: October 15, 2010

Dear Ms. Calzetta:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092571

Gyrus ACMI Inc. BiCoag Hemostasis probe
Gyrus ACMI Inc
136 Turnpike Road
Southborough, MA 01772

Traditional 510(k) Notification
Statement of Intended Use

Device Name: Gyrus ACMI Inc. BiCoag Hemostasis Probe

510(k) Number:

Indications for use:

OCT 2 0 2010

The Gyrus ACMI Inc. BiCoag Hemostasis Probe is intended for coagulation of active bleeding lesions in the upper or lower gastrointestinal tract during endoscopic procedures.

Prescription Use: __ X __ OR Over-the-Counter Use: _____

(Per 21 CFR 801.109)

(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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092571