JUL 16 2002

ACMI

Premarket Notification 510(k) Summary
(as required by section 807.92(c))

510K Number: K012018

Submitter: Frank J. Fucile, Director, Regulatory Affairs
ACMI Corporation
136 Turnpike Road
Southborough, MA 01772 USA
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Date prepared: July 10, 2002

Proprietary Name: ACMI BICAP COAG Bipolar Laparoscopy Probe

Common Name: Laparoscopy Probe

Classification Name: Endoscopic electrosurgical unit and accessories, 21 CFR 876.4300

Substantially Equivalent Devices:

The BICAP COAG Bipolar Laparoscopy Probe to the ACMI Bipolar Hemostatic Electrode (K803214) and the Cabot Medical Surgiflex Suction-Irrigation Probe (K932626).

Description of Device:

The 5 mm ACMI BICAP COAG Bipolar Laparoscopy Probe (32 cm working length) is designed for laparoscopic coagulation, irrigation, and aspiration. The RF current path within the patient is identical to standard bipolar; consequently, the need for a patient dispersive electrode is eliminated. The current flow through the tissue is localized to help prevent a thermal effect distant from the surgical site.

The BICAP COAG Bipolar Laparoscopy Probe connects to ACMI Surgiflex WAVE suction-irrigation tubing sets. Use of the BICAP COAG Probe can help reduce operating room time by reducing the number of instrument exchanges. With a bipolar tip at the end of the suction-irrigation shaft, hemostasis, blunt dissection, irrigation, and aspiration may

be readily performed without withdrawing the instrument. The oval tip design of the probe provides easy, less traumatic access to ovarian and tubal cysts and other difficult to reach areas. BICAP COAG instruments are compatible with most bipolar generators, allowing them to be used with existing equipment.

Intended Use:

The BICAP COAG Bipolar Laparoscopy Probe is indicated for use in laparoscopic procedures to provide bipolar coagulation, blunt dissection, irrigation, and aspiration. The BICAP COAG Probe may be used in a variety of gastrointestinal, urological and gynecological procedures.

Summary Comparison of Technological Characteristics Compared to Predicate Devices:

The ACMI Bipolar Hemostatic Electrode is virtually identical to the BICAP COAG Bipolar Laparoscopy Probe in design and functions (coagulation, blunt dissection, suction, irrigation) except that the Bipolar Hemostatic Electrode was intended for use only in gastrointestinal procedures, while the BICAP COAG Probes are intended for general laparoscopic use including gastrointestinal, urological and gynecological procedures.

The Cabot Medical Surgiflex Suction-Irrigation Probe is similar to the BICAP COAG Probe in regard to functions (coagulation, blunt dissection, suction, irrigation) and both are intended for general laparoscopic use including gastrointestinal, urological and gynecological procedures. The primary difference is that the Surgiflex Probe is monopolar while the BICAP COAG operates as a bipolar device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2002

ACMI Corporation
Frank J. Fucile
Director, Regulatory Affairs
136 Turnpike Road
Southborough, Massachusetts 01722

Re: K012018
Trade Name: ACMI BICAP COAG Bipolar Laparoscopy Probe
Regulation Number: 878.4400
Regulation Name: Electrosurgical Device, Cutting & Coagulation & Accessories
Regulatory Class: II
Product Code: GEI
Dated: May 2, 2002
Received: May 3, 2002

Dear Mr. Fucile:

We have reviewed your Section 510(k) premarket 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 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

K012018

BICAP COAG Bipolar Laparoscopy Probe

INDICATIONS FOR USE STATEMENT

Premarket Notification Number K012018

Device Name: BICAP COAG Bipolar Laparoscopy Probe

The BICAP COAG Bipolar Laparoscopy Probe is indicated for use in laparoscopic procedures to provide bipolar coagulation, blunt dissection, irrigation, and aspiration. The BICAP COAG Probe may be used in a variety of gastrointestinal, urological and gynecological procedures.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012018