K031001

MAY 21 2003

510(k) Summary of Safety and Effectiveness
ACMI Corporation
ACMI VISTA CTR BIPOLAR LOOP ELECTRODE
(Page 1 of 2)

General Information

Manufacturer:	ACMI Corporation 136 Turnpike Rd. Southborough, MA. 01772-2104
FDA Establishment Registration:	2020483
Contact Person:	Gabriel J. Muraca, Jr. Senior Regulatory Affairs Specialist
Date Prepared:	March 28, 2003

Device Description

Classification Name:	21CFR 878.4400 - Electrosurgical cutting and coagulation device and accessories.
Trade Name:	ACMI Vista CTR Bipolar Loop Electrode
Generic/Common Name:	Electrosurgical cutting and Coagulation device and Accessories

Predicate Devices

ACMI USA Elite System Right Angle Cutting Loop Electrode	-	K973820
ACMI Bipolar Resectoscope & Loop Electrode	-	K021166

Intended Uses

Intended for use in patients requiring endoscopic surgery for general urological tissue resection, ablation, and excision and hemostasis of blood vessels. These procedures include Bladder Tumor Diagnosis and Resection, Transurethral Prostatic and Bladder Biopsy, Transurethral Prostatic Resection, Removal of Ureteral Calculus, and Treatment of Vesical Neck Constriction.

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(Page 2 of 2)

Product Description

The Vista CTR Bipolar Loop Electrode is a double loop bipolar electrosurgical device, designed to work with currently marketed Electrosurgery Systems. These systems consist of an electrosurgical generator (the Controller), a reusable or disposable Cable (Bipolar Active Cord) and a Bipolar Resectoscope System.

Summary of Safety and Effectiveness

This Special 510(k) proposes a modification in two materials of the electrode, a change in the packaging, sterilization method, and a change in the labeling to indicate the new sterilization method. The indications for use, principles of operation, of the Vista CTR Bipolar Loop Electrode remain the same as in the predicate devices.

The proposed modifications for the Vista CTR Bipolar Loop Electrode, as described in this submission, are substantially equivalent to the predicate devices. The proposed modification in materials, packaging, sterilization, and labeling are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2003

Gabriel J. Muraca, Jr.
Senior Regulatory Affairs Specialist
ACMI Corporation
136 Turnpike Road
SOUTHBOROUGH MA 01772-2104

Re: K031001
Trade/Device Name: ACMI® Vista CTR Bipolar Loop Electrode
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: 78 FAS
Dated: April 30, 2003
Received: May 1, 2003

Dear Mr. Muraca:

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); 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 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Device Name: **ACMI VISTA CTR BIPOLAR LOOP ELECTRODE**

510(k) Number: K031001

Indications for Use:

Intended for use in patients requiring endoscopic surgery for general urological tissue resection, ablation, and excision and hemostasis of blood vessels. These procedures include Bladder Tumor Diagnosis and Resection, Transurethral Prostatic and Bladder Biopsy, Transurethral Prostatic Resection, Removal of Ureteral Calculus, and Treatment of Vesical Neck Constriction.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031001