K022543

Pg 1 of 2

AUG 3 0 2002

510(k) Summary

ArthroCare Corporation
ArthroCare® Bipolar Loop Electrosurgery System

General Information

Submitter Name/Address:	ArthroCare Corporation 680 Vaqueros Avenue Sunnyvale, CA 94085-2936
Phone Number:	(408) 736-0224
Contact Person:	Bruce Prothro Vice President, Operational Planning, Quality and Regulatory Affairs
Date Prepared:	July 30, 2002

Device Description

Trade Name:	ArthroCare® Bipolar Loop Electrosurgery System
Generic/Common Name:	Electrosurgical Device and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

Predicate Devices

ArthroCare® Bipolar Loop Electrosurgery System	K955531 and K010568

Product Description

The ArthroCare® Bipolar Loop Electrosurgery System is a bipolar, high frequency electrosurgical system consisting of three components: an electrosurgical generator called the Controller; a family of disposable, bipolar, single use Wands; and a reusable Patient Cable.

K022543

pg 2 of 2

Intended Uses

The ArthroCare® Bipolar Loop Electrosurgery System is a bipolar electrosurgical device intended for use in patients requiring endoscopic surgery for general urological procedures. Urological tissue can be resected using this System, such as the prostate, in procedures including transurethral prostatectomy (TURP) and transurethral incisions in the prostate (TUIP), as well as non-malignant tumors of the bladder wall. The System has been shown to be effective in tissue resection, ablation, and excision, as well as in hemostasis of blood vessels. It is intended for endoscopic procedures using saline solution, Ringer's lactate, or other conductive solutions as irrigants, under direct or video-assisted fiberoptic visualization.

Substantial Equivalence

This Special 510(k) proposes a modification in the performance specifications, dimensional specifications, and labeling for the Bipolar Loop Electrosurgery System, which was previously cleared in K955531 on February 21, 1996 and K010568 on March 27, 2001. The indications for use, technology, principle of operation, materials, packaging, and sterilization parameters of the ArthroCare Bipolar Loop Electrosurgery System remain the same as in the predicate cleared 510(k).

Summary of Safety and Effectiveness

The modified Bipolar Loop Electrosurgery System, as described in this Special 510(k), is substantially equivalent to the predicate device. The proposed modifications in performance specifications, dimensional specifications, and labeling are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2002

Ms. Valerie Defiesta-Ng
Director, Regulatory Affairs
ArthroCare® Corporation
680 Vaqueros Avenue
SUNNYVALE CA 94085

Re: K022543
Trade/Device Name: ArthroCare® Bipolar Loop Electrosurgery System
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Codes: 78 FAS and KNS
Dated: July 30, 2002
Received: August 1, 2002

Dear Ms. Defiesta-Ng:

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

Indications for Use Statement

Device Name: ArthroCare® Bipolar Loop Electrosurgery System

510(k) Number: K022543

Indications for Use:

The ArthroCare® Bipolar Loop Electrosurgery System is a bipolar electrosurgical device intended for use in patients requiring endoscopic surgery for general urological procedures. Urological tissue can be resected using this System, such as the prostate, in procedures including transurethral prostatectomy (TURP) and transurethral incisions in the prostate (TUIP), as well as non-malignant tumors of the bladder wall. The System has been shown to be effective in tissue resection, ablation, and excision, as well as in hemostasis of blood vessels. It is intended for endoscopic procedures using saline solution, Ringer's lactate, or other conductive solutions as irrigants, under direct or video-assisted fiberoptic visualization.

(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 K022543