JAN 1 8 2002

ArthroCare CORPORATION

510(k) Summary

K014222

ArthroCare Corporation
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, Regulatory Affairs, Quality Assurance, and Clinical Research
Date Prepared:	December 20, 2001

Device Description

Trade Name:	ArthroCare® 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® Electrosurgery Wands	K012519

Product Description

The 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.

595 North Pastoria Avenue • Sunnyvale, CA 94085 • (408) 736-0224 • Fax: (408) 736-0226

Intended Uses

The Electrosurgery System is intended for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in open, laparoscopic, and endoscopic general surgery and general gynecology procedures. Representative procedures may include the following:

General Surgery
cholecystectomy
lysis of adhesions
upper GI
GI (other)
splenectomy
thyroidectomy
herniorrhaphy
breast biopsy
bowel resection
pelvic adhesiolysis
removal of lesions
removal of polyps
tumor biopsy
Gynecological Surgery
lysis of adhesions
hysterectomy
salpingo-oophorectomy
burch colposuspension
myomectomy
endometriosis
ovariohysterectomy
removal of tumors

Substantial Equivalence

This Special 510(k) proposes a modification in the performance specifications, dimensional specifications, and labeling for the Electrosurgery System, which was previously cleared in K012519 on October 25, 2001. The indications for use, technology, principle of operation, materials, packaging, and sterilization parameters of the Electrosurgery System remain the same as in the predicate cleared 510(k).

Summary of Safety and Effectiveness

The modified 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

JAN 18 2002

Mr. Bruce Prothro
Vice President, Regulatory Affairs,
Quality Assurance, and Clinical Research
ArthroCare Corporation
595 North Pastoria Avenue
Sunnyvale, California 94085

Re: K014222
Trade/Device Name: ArthroCare® Electrosurgery System
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 20, 2001
Received: December 26, 2001

Dear Mr. Prothro:

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 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,

for Mark N Melkerson

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

Indications for Use Statement

Device Name Electrosurgery System

510(k) Number: K 014 222

Indications for Use:

The Electrosurgery System is intended for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in open, laparoscopic, and endoscopic general surgery and general gynecology procedures. Representative procedures may include the following:

General Surgery
cholecystectomy
lysis of adhesions
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pelvic adhesiolysis
removal of lesions
removal of polyps
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Gynecological Surgery
lysis of adhesions
hysterectomy
salpingo-oophorectomy
burch colposuspension
myomectomy
endometriosis
ovariohysterectomy
removal of tumors

(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)

for Mark N Milhous

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

510(k) Number K014222