APR - 9 2002

ArthroCare CORPORATION

510(k) Summary

ArthroCare Corporation
ArthroCare® System 2000
ArthroCare® Orthopedic Electrosurgery System
ArthroCare® Bipolar Loop

K020832

General Information

Submitter Name/Address:	ArthroCare Corporation 680 Vaqueros Avenue Sunnyvale, CA 94085-2936
Establishment Registration Number:	2951580
Contact Person:	Valerie Defiesta-Ng Director, Regulatory Affairs
Date Prepared:	March 13, 2002

Device Description

Trade Name:	ArthroCare System 2000 ArthroCare Orthopedic Electrosurgery System ArthroCare Bipolar Loop
Generic/Common Name:	Electrosurgical Device and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

Predicate Devices

ArthroCare System 2000, ArthroCare Orthopedic Electrosurgery System, and ArthroCare Bipolar Loop	K011634

Product Description

The ArthroCare Wands are bipolar, single use, high frequency electrosurgical devices designed for specific indications in neurosurgical, spinal, and urological procedures.

680 Vaqueros Avenue • Sunnyvale, CA 94085 • (408) 736-0224 • Fax: (408) 736-0226

Intended Use

ArthroCare System 2000

- The ArthroCare System 2000 is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in orthopedic, arthroscopic, spinal, and neurosurgical procedures.

ArthroCare Orthopedic Electrosurgery System

- The ArthroCare Orthopedic Electrosurgery System is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in in orthopedic, arthroscopic, and spinal procedures.

ArthroCare Bipolar Loop

- The ArthroCare Bipolar Loop is indicated for resection, ablation, and excision, as well as hemostasis of blood vessels in patients requiring endoscopic surgery for general urological procedures including transurethral prostatectomy (TURP), transurethral incisions in the prostate (TUIP), and non-malignant tumors of the bladder wall.

Substantial Equivalence

This Special 510(k) proposes modifications in materials and labeling for the ArthroCare Wands, which were previously cleared under K011634 on June 19, 2001. The indications for use, technology, principle of operation, performance and dimensional specifications, packaging, and sterilization parameters of the Wands remain the same as in the predicate cleared 510(k).

Summary of Safety and Effectiveness

The modified Wands, as described in this submission, are substantially equivalent to the predicate Wands. The proposed modification in materials 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

APR - 9 2002

Ms. Valerie Defiesta-Ng
Director
Regulatory Affairs
ArthroCare Corporation
680 Vaqueros Avenue
Sunnyvale, California 94085

Re: K020832
Trade/Device Name: ArthroCare® System 2000, ArthroCare® Orthopedic Electrosurgery System and ArthroCare® Bipolar Loop
Regulation Number: 878.440 and 888.1100
Regulation Name: Electrosurgical Device, Cutting & Coagulation & Accessories and Arthroscope and Accessories
Regulatory Class: II
Product Code: GEI and HRX
Dated: January 4, 2002
Received: January 7, 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 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: ArthroCare® System 2000
ArthroCare® Orthopedic Electrosurgery System
ArthroCare® Bipolar Loop

510(k) Number: K 020832

Indications for use:

ArthroCare System 2000

- The ArthroCare System 2000 is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in orthopedic, arthroscopic, spinal, and neurosurgical procedures.

ArthroCare Orthopedic Electrosurgery System

- The ArthroCare Orthopedic Electrosurgery System is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in in orthopedic, arthroscopic, and spinal procedures.

ArthroCare Bipolar Loop

- The ArthroCare Bipolar Loop is indicated for resection, ablation, and excision, as well as hemostasis of blood vessels in patients requiring endoscopic surgery for general urological procedures including transurethral prostatectomy (TURP), transurethral incisions in the prostate (TUIP), and non-malignant tumors of the bladder wall.

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

510(k) Number K020832