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510(k) Summary

K053297

ArthroCare Corporation

ArthroCare 8000S Coblator Surgery System

General Information

Submitter Name/Address:	ArthroCare Corporation 680 Vaqueros Avenue Sunnyvale, CA 94085-2936
Phone Number:	(408) 736-0224
Contact Person:	Valerie Defiesta-Ng Director, Regulatory Affairs
Date Prepared:	November 23, 2005

Device Description

Trade Name:	ArthroCare 8000S Coblator Surgery System
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	K001588

Product Description

The ArthroCare 8000S Coblator Surgery 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.

Intended Uses

The ArthroCare 8000S Coblator Surgery System is indicated for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in orthopedic, arthroscopic, spinal, and neurological procedures.

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Substantial Equivalence

This Special 510(k) proposes a modification in the performance specifications, dimensional specifications, and labeling for the ArthroCare System 2000, which was previously cleared in K001588 on August 17, 2000. The indications for use, technology, principle of operation, materials, packaging, and sterilization parameters of the ArthroCare 8000S Coblator Surgery System remain the same as in the predicate cleared 510(k).

Summary of Safety and Effectiveness

The ArthroCare 8000S Coblator Surgery 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

DEC 6 2005

Valerie Defiesta-Ng
Director, Regulatory Affairs
ArthroCare Corporation
680 Vaqueros Avenue
Sunnyvale, California 94085-2936

Re: K053297
Trade/Device Name: ArthroCare 8000S Coblator Surgery System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, GXI
Dated: November 23, 2005
Received: November 25, 2005

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

Barbara Bucklin MD
for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K 053297

Device Name: ArthroCare 8000S Coblator Surgery System

Indications for Use:
The ArthroCare 8000S Coblator Surgery System is intended for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in orthopedic, arthroscopic, spinal, and neurological procedures.

Prescription Use (21 CFR 801 Subpart D)	X	OR	Over-the-Counter Use (21 CFR 801 Subpart C)	____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ausel MD for MKM

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

510(k) Number K053297