K100353

MAY 13 2010

510(k) Summary

ArthroCare Corporation
ArthroCare® Coblator IQ™ Perc-D® SpineWand®

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:	February 11, 2010

Device Description

Trade Name:	ArthroCare® Coblator IQ™ Perc-D® SpineWand®
Generic/Common Name:	Electrosurgical Device and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

Predicate Devices

ArthroCare Perc-D SpineWand	K053447 (December 27, 2005)
ArthroCare Perc-D SpineWand	K030954 (April 16, 2003)
ArthroCare Perc-D SpineWand	K020621 (March 28, 2002)
ArthroCare Perc-D SpineWand	K010811 (May 30, 2001)

Product Description
The Wands are bipolar, single use, high frequency electrosurgical devices.

The Coblator IQ Perc-D SpineWands include the following Wands: Coblator IQ DC SpineWand, Coblator IQ DLR SpineWand, and the Coblator IQ DLG SpineWand.

Intended Use
The ArthroCare® Coblator IQ™ Perc-D® SpineWand® is indicated for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs.

Substantial Equivalence

This Special 510(k) proposes modifications to the performance specifications and labeling of the ArthroCare® Coblator IQ™ Perc-D® SpineWand®. The indications for use, materials, technology, sterilization, and principle of operation of the SpineWands remain the same as in the predicate device.

Summary of Safety and Effectiveness

The proposed modifications to the SpineWands are not substantial changes, and do not significantly affect the safety or efficacy of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ArthroCare® Corporation
% Ms. Valerie Defiesta-Ng
680 Vaqueros Avenue
Sunnyvale, CA 94085-3523

MAY 13 2010

Re: K100353
Trade/Device Name: ArthroCare® Coblator IQ™ Perc-D® SpineWand®
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: February 11, 2010
Received: February 12, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K_____

Device Name: ArthroCare® Coblator IQ™ Perc-D® SpineWand®

Indications for use:

The ArthroCare® Coblator IQ™ Perc-D® SpineWand® is indicated for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-the-Counter Use (21 CFR 807 Subpart C)	____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K100353