K123353

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510(k) Summary

ArthroCare® Corporation

COBLATOR IQ™ ENT SYSTEM

APR 5 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

Submitter Name:	ArthroCare Corporation
Address	7000 West William Cannon Drive Austin, TX 78735
Contact Person:	Mitchell Dhority Vice President, Clinical and Regulatory Affairs
Date Prepared:	October 29, 2012

Device System Names/Components

Proprietary:	Coblator IQ™ ENT System
Common:	ENT System
Classification:	Class II
Product Code:	GEI
CFR Section:	21 CFR 878.4400

Predicate Device

ArthroCare ENT Plasma Wands	K070374 (April 25, 2007) K063538 (December 1, 2006) K033257 (October 29, 2003) K014290 (March 28, 2002)
ArthroCare Coblator IQ System (Controller)	K091674 (January 15, 2010)

Description

The ArthroCare Coblator IQ ENT System (CIQ System) is comprised of eight ArthroCare Coblator IQ ENT Plasma Wands (CIQ Wands) and the ArthroCare Coblator IQ Controller (CIQ Controller).

The CIQ Wands are bipolar, single use, radiofrequency-based electrosurgical devices designed for use with the CIQ Controller for specific indications in otorhinolaryngology (ENT) procedures.

The CIQ Controller is a bipolar, high frequency electrosurgical generator with an integrated peristaltic pump for saline delivery.

Intended Use/Indications For Use

The ArthroCare® Coblator IQ™ ENT System is indicated for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including:

- Adenoidectomy
- Head, Neck, Oral, and Sinus Surgery
- Myringotomy with Effective Hemorrhage Control
- Nasopharyngeal/Laryngeal indications including Tracheal Procedures, Laryngeal Polypectomy, and Laryngeal Lesion Debulking
- Papilloma Keloids
- Submucosal Tissue Shrinkage
- Traditional Uvulopalatoplasty (RAUP)
- Tissue in the Uvula/Soft Palate for the treatment of Snoring
- Cysts
- Mastoidectomy
- Nasal Airway Obstruction by Reduction of Hypertrophic Nasal Turbinates
- Neck Mass
- Submucosal Palatal Shrinkage
- Tonsillectomy (including palatine tonsils)
- Tumors

Performance Testing – Bench

Bench testing was conducted to evaluate the performance of the Coblator IQ ENT System compared to the predicate devices. The test results demonstrate that the Coblator IQ ENT System meets all design and performance specifications.

Performance Testing – Animal

Pre-Clinical animal studies were conducted to compare the tissue effects using the Coblator IQ ENT System as compared to the predicate devices. Based on the test results, the proposed devices are substantially equivalent to the predicate devices.

Performance Testing - Clinical

No clinical data are included in this submission.

Summary

The ArthroCare Coblator IQ ENT System (CIQ System) is comprised of eight ArthroCare Coblator IQ ENT Wands (CIQ Wands) and the ArthroCare Coblator IQ Controller (CIQ Controller).

The modified CIQ Wands are substantially equivalent to the predicate ArthroCare ENT Plasma Wands. The modification to performance specifications, materials, and labeling are minor changes, and do not affect the safety or efficacy of the devices.

There have also been minor software changes to the CIQ Controller cleared in 2010. However, these changes do not affect the safety or efficacy of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Arthrocare Corporation
% Mr. Mitchell Dhority
Vice President, Clinical and Regulatory Affairs
7000 West William Cannon Drive
Austin, Texas 78735

Letter dated: April 5, 2013

Re: K123353
Trade/Device Name: ArthroCare® Coblator IQ™ ENT System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 12, 2013
Received: March 27, 2013

Dear Mr. Dhority:

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); 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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson -S

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

Enclosure

Indications for Use

510(k) Number (if known): K123353

Device Name: ArthroCare® Coblator IQ™ ENT System

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/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)

Joshua C. Nipper -S For

(Division Sign-Off)
Division of Surgical Devices

510(k) Number K123353