OCT 15 2008

K082666

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510(k) Summary

ArthroCare Corporation
ArthroCare® System 12000

General Information

Submitter Name/Address:	ArthroCare Corporation 680 Vaqueros Avenue Sunnyvale, CA 94085-3523
Establishment Registration Number:	2951580
Contact Person:	Valerie Defiesta-Ng Director, Regulatory Affairs
Date Prepared:	September 11, 2008

Device Description

Trade Name:	ArthroCare® System 12000
Generic/Common Name:	Electrosurgical Device and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (Class II, 21 CFR 878.4400, Product Code GEI)

Predicate Devices

ArthroCare® System 12000	K071709

Product Description

The ArthroCare® System 12000 is a bipolar, high frequency, electrosurgical generator called the Controller that is intended to be used with a family of disposable, bipolar, single use Wands.

Intended Uses

The ArthroCare System 12000 is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures:

Arthroscopic and Orthopedic Procedures	**Joint Specific or All Joints (ankle, elbow, hip, knee, shoulder, and wrist)**
Ablation and Debridement	
• ACL/PCL	Knee
• Acromioplasty	Shoulder
• Articular Cartilage	All Joints
• Bursectomy	All Joints
• Chondroplasty	All Joints
• Fascia	All Joints
• Ligament	All Joints
• Notchplasty	Knee
• Scar Tissue	All Joints
• Soft Tissue	All Joints
• Subacromial Decompression	Shoulder
• Synovectomy	All Joints
• Tendon	All Joints
Excision and Resection	
• Acetabular Labrum	Hip
• Articular Labrum	All Joints
• Capsule	All Joints
• Capsular Release	Knee
• Cartilage Flaps	Knee
• Cysts	All Joints
• Discoid Meniscus	Knee
• Frozen Shoulder Release	Shoulder
• Glenoidale Labrum	Shoulder
• Lateral Release	Knee
• Ligament	All Joints
• Loose Bodies	All Joints
• Meniscal Cystectomy	Knee
• Meniscectomy	Knee

Continued

Arthroscopic and Orthopedic Procedures	Joint Specific or All Joints (ankle, elbow, hip, knee, shoulder, and wrist)
• Plica Removal	All Joints
• Scar Tissue	All Joints
• Soft Tissue	All Joints
• Synovial Membrane	All Joints
• Tendon	All Joints
• Triangular Fibrocartilage (TFCC)	Wrist
• Villusectomy	Knee
Coagulation	
• ACL/PCL	Knee
• Articular Cartilage	All Joints
• Carpal Ligaments	Wrist
• Glenohumeral Capsule	Shoulder
• Ligament	All Joints
• Medial Retinaculum	Knee
• Rotator Cuff	Shoulder
• Tendon	All Joints
• Wrist Tendons	Wrist

Substantial Equivalence

This Special 510(k) proposes a modification in the performance specifications and labeling for the ArthroCare System 12000, which was previously cleared in K071709 on August 7, 2007. The indications for use, technology, principle of operation, materials, packaging, and sterilization parameters of the ArthroCare System 12000 remain the same as in the predicate cleared 510(k).

Summary of Safety and Effectiveness

The modified ArthroCare System 12000, as described in this Special 510(k), is substantially equivalent to the predicate device. The proposed modifications in performance 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

OCT 15 2008

ArthroCare Corporation
% Ms. Valerie Defiesta-Ng
Director, Regulatory Affairs
680 Vaqueros Avenue
Sunnyvale, California 94085-3523

Re: K082666
Trade/Device Name: ArthroCare System 12000
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 25, 2008
Received: September 29, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K082666

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Indications for Use Statement

Device Name ArthroCare System 12000

510(k) Number: K_____

Indications for Use:

The ArthroCare System 12000 is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures:

Arthroscopic and Orthopedic Procedures	**Joint Specific or All Joints (ankle, elbow, hip, knee, shoulder, and wrist)**
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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices
510(k) Number K082666

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) X OR Over-the-Counter Use ____

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