

K071709
510(k) Summary

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ArthroCare Corporation
ArthroCare® System 12000

AUG - 7 2007

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: June 20, 2007

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

K032504

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) |
|--|---|
| <i>Ablation and Debridement</i> | |
| • 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 |
| <i>Excision and Resection</i> | |
| • 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

In establishing substantial equivalence to the predicate device, ArthroCare compared the indications for use, dimensional specifications, and performance specifications of the subject device and the predicate device. Additionally, performance testing has been completed to demonstrate the substantial equivalence of the ArthroCare System 12000 to the predicate device. The performance testing and device comparison demonstrated that the subject device is substantially equivalent to the predicate device, and is safe and effective for its intended use.

Summary of Safety and Effectiveness

The ArthroCare System 12000, as described in this premarket notification 510(k), is substantially equivalent to the predicate device. The differences in performance specifications, and labeling are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the System.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2007

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

Re: K071709

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: June 20, 2007

Received: June 22, 2007

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.

Page 2 – Ms. Valerie Defiesta-Ng

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 (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

Indications for Use Statement

Device Name ArthroCare System 12000

510(k) Number: K 071709

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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:

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Mark A. Wilkerson

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

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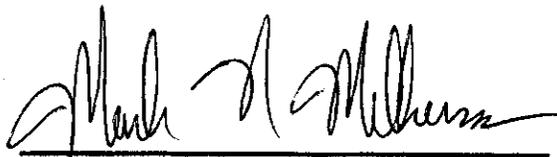
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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



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

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