JUN 6 2002

ArthroCare CORPORATION

510(k) Summary

K021519

ArthroCare Corporation
ArthroCare® Timer

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:	May 9, 2002

Device Description

Trade Name:	ArthroCare® Timer
Generic/Common Name:	Electrosurgical Device and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

Predicate Devices

ArthroCare® ArthroWands	K020557

Product Description

The ArthroCare Timer is an accessory that can be used with ArthroCare's Electrosurgery System. It is designed to control the duration of therapy treatment during soft tissue ablation procedures.

Intended Uses

The ArthroCare Timer is an accessory, supplied separately, that can be used with the Electrosurgery System in the following indications:

- The ArthroCare ArthroWands are indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures:

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Arthroscopic and Orthopedic Procedures	Joint Specific or All Joints (ankle, elbow, hip, knee, shoulder, and wrist)
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 to modify the performance specifications and labeling for the Electrosurgery System, which was previously cleared in K020557 on March 21, 2002. The indications for use, technology, principle of operation, materials, packaging, and sterilization parameters of the entire Electrosurgery System remain the same as in the predicate cleared 510(k).

Summary of Safety and Effectiveness

The addition of the ArthroCare Timer to the Electrosurgery System, as described in this Special 510(k), is substantially equivalent to the predicate devices. The proposed addition of the ArthroCare Timer 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

JUN 6 2002

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

Re: K021519
Trade/Device Name: ArthroCare® Timer
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: May 9, 2002
Received: May 10, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
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® Timer

510(k) Number: K021519

Indications for Use:

- The ArthroCare ArthroWands are 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
• Facia	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

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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

(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 [illegible]storative and Neurological D[illegible]ces

510(k) Number K021519

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