

DEC - 9 1999

**510(k) Summary of
Safety and Effectiveness
ArthroCare, Corporation
ArthroCare Orthopedic Electrosurgery System**

K992581

General Information

Manufacturer: ArthroCare, Corporation
595 North Pastoria Avenue
Sunnyvale, CA 94086-2916

Establishment Registration Number: 2951580

Contact Person: Bruce Prothro, Vice President Regulatory
Affairs and Quality Assurance

Date Prepared: July 29, 1999

Device Description

Classification Name: Electrosurgical Cutting and Coagulation
Device and Accessories (21 CFR 878.4400)

Trade Name: ArthroCare Orthopedic Electrosurgery System

Generic/Common Name: Electrosurgical Device and Accessories

Predicate Devices

ArthroCare Arthroscopic Electrosurgery System 970	K943450
ArthroCare Arthroscopic Electrosurgery System 980 (Model 2000)	K963123
ArthroCare ENTec Surgery System	K973478
Ellman Surgitron	K980170

Intended Use

The ArthroCare Orthopedic Electrosurgery System is indicated for resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, and spinal procedures.

Product Description

The ArthroCare Orthopedic Electrosurgery System is a bipolar, high frequency electrosurgical system designed for use in orthopedic procedures where ablation and coagulation of soft tissue and hemostasis of blood vessels is desired. The System

K99 2581

consists of three components: an electrosurgical generator called the Controller, the disposable Wand, and the reusable Cable. The Controller utilizes radio frequency (RF) energy as a power source. RF energy is delivered to the patient via the Cable and the Wand. The Cable is designed to attach to the Controller and Wand for patient treatment. The single use, sterile Wand is the patient contacting component of the System. The Wand configuration ranges from single to multiple electrodes incorporating straight, screen, loop, and sheet shaped electrodes. The ArthroCare Orthopedic Electrosurgery System uses bipolar technology in the design of the Wand eliminating the need for a patient contacting dispersive pad used in monopolar devices.

Substantial Equivalence

The ArthroCare Arthroscopic Electrosurgery System 980 (Model 2000) was previously cleared under K963123 on October 8, 1996 for the following indications: soft tissue resection and ablation during arthroscopic surgical procedures of the knee, shoulder, ankle, elbow, hip, and wrist. This premarket notification purposes to change the product name and expand the indication to include orthopedic and spinal procedures. The proposed indications for the ArthroCare Orthopedic Electrosurgery System are: resection, ablation and coagulation of soft tissues and hemostasis of blood vessels, in orthopedic, arthroscopic, and spinal procedures.

The ArthroCare Orthopedic Electrosurgery System has not modified the technology, principle of operation, design, manufacturing operations, and/or sterilization since the original approval of the ArthroCare Arthroscopic Electrosurgery System 980 (Model 2000) on October 8, 1996 (K963123) or the ArthroCare ENTec Surgery System on January 9, 1998 (K973478). The Arthrocare Arthroscopic Electrosurgery System 980 (Model 2000) and the ArthroCare ENTec Electrosurgery System are modifications of the initial predicate device, the ArthroCare Arthroscopic Electrosurgery System 970, which was cleared on March 10, 1995 (K943450). Additionally, the ArthroCare Orthopedic Electrosurgery System utilizes technology that is substantially equivalent to electrosurgical devices currently used in spinal applications such as the Ellman Surgitron cleared June 19, 1998 (K980170).

Summary of Safety and Effectiveness

In establishing substantial equivalence to the predicate devices, ArthroCare evaluated the indications for use, materials incorporated, product specifications and energy requirements of those systems. The expanded indication to include orthopedic and spinal procedures does not raise any new issues of safety or efficacy.



DEC - 9 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Bruce Prothro
Vice President, Regulatory Affairs and Quality Assurance
ArthroCare Corporation
595 North Pastoria Avenue
Sunnyvale, California 94086

Re: K992581
Trade Name: Orthopedic Electrosurgery System
Regulatory Class: II
Product Code: GEI
Dated: November 3, 1999
Received: November 5, 1999

Dear Mr. Prothro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Mr. Bruce Prothro

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


Siv James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Name: ArthroCare Orthopedic Electrosurgery System
510(k) Number: K99 2581

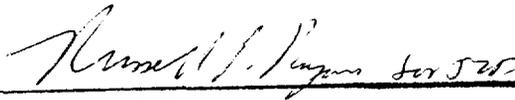
Indications for use:

The ArthroCare Orthopedic Electrosurgery System is indicated for resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, and spinal procedures.

(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 Devices
510(k) Number K99 2581