

MAY 28 1997

## **X. Summary of Safety and Effectiveness**

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The ArthroCare Urologic Monopolar Electrosurgery Loop is a high frequency electro-surgical device intended for use in general urological surgery to resect soft tissue and provide hemostasis. Predicate electrode products and electro-surgical generators have been marketed since the 1950's by several different manufacturers such as Circon ACMI and Karl Storz. Other monopolar loops and rollerball/barrel electrodes have been cleared for market via 510(k)'s, such as the rollerballs manufactured by ProSurge and Karl Storz-America, Inc. These products have been demonstrated to be safe and effective in resecting soft tissue during urological surgical procedures.

The materials used in the ArthroCare Urologic Monopolar Electrosurgery Loop are virtually identical to those used in the ArthroCare Arthroscopic Electrosurgery System (K943450). Predicate devices use either stainless, tungsten or titanium for the wire material of their electro-surgical electrodes.

By virtue of design, materials and function, the ArthroCare Urologic Monopolar Electrosurgery Loop is substantially equivalent to the predicate devices currently marketed in the United States.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 28 1997

Mr. Cheryl L. Shea  
Director - Regulatory Affairs/Quality Assurance  
ArthroCare, Corporation  
595 North Pastoria Avenue  
Sunnyvale, California 94086

Re: K970526  
ArthroCare Urologic Monopolar Electrosurgery Loop  
Dated: April 15, 1997  
Received: April 17, 1997  
Regulatory class: II  
21 CFR §876.4300/Product code: 78 FAS

Dear Mr. Shea:

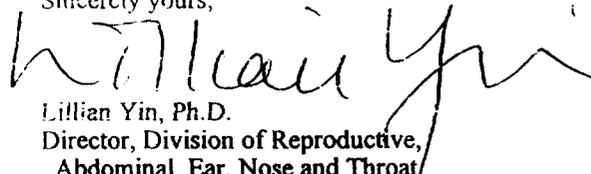
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Premarket 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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) 594-4616. 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,



Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

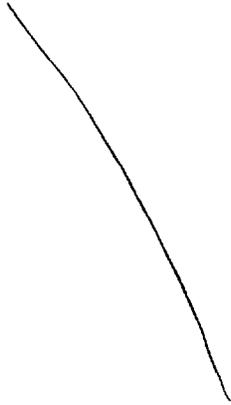
Enclosure



510(k) Number: K970526  
Device Name: **ArthroCare Monopolar Loop**

**Indications for Use:**

The ArthroCare Monopolar Loop is indicated in patients requiring endoscopic soft tissue ablation and resection in general urological surgical procedures.



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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R. Rathjens  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K970526

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_