OCT 25 1999

HYDROCISION, INC.
220 Ballardvale Street
Wilmington, MA 01887
(978) 657- 0020

510K Summary K993009

1. Sponsor Name

   HydroCision, Inc.
   220 Ballardvale Street
   Willmington, MA 01887
   978 657 0020

2. Device Name

   Proprietary Name: HydroCision ArthroJet System with Cautery
   Common/Usual Name: Arthroscope and accessories
   Electrosurgical Cutting and Coagulation Device and Accessories
   Classification Name: Arthroscope and accessories
   Electrosurgical Cutting and Coagulation Device and Accessories

3. Identification of Predicate or Legally Marketed Device

   The HydroCision ArthroJet System with Cautery substantially equivalent in intended use and/or function to the following predicate devices: the HydroCision ArthroJet System (K982266) and the Valleylab Electrosurgical Pencil (K861112)/Valleylab Electrode (K791638), and the Kirwan Suction Coagulator (K965421). It is also substantially equivalent to the ArthroCare Electrosurgery System (K961323) in that the ArthroCare unit provides all the above functions in the same unit and handpiece.

4. Device Description

   The HydroCision ArthroJet System with Cautery is a surgical device which provides cutting, tissue removal, and electrocauterization in the same tool. The HydroCision ArthroJet System with Cautery uses the same system as the FDA approved HydroCision ArthroJet System (K982266) with the addition of a bipolar cauterization function at the distal tip of the handpiece.

   The ArthroJet System with Cautery is compatible with standard RF generators which provide bipolar energy output (with a voltage of less than or equal to 1,000 volts p-p).

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The ArthroJet System with Cautery operates in a saline or Ringer's Lactate environment. These typical arthroscopic irrigation fluids are conductive and serve as a path for the electrical energy to return to the generator, as described. The hand piece and electrical connections are protected from the possibility of shorting should spillage of conductive fluid onto the unit occur.

The bipolar cables used in the ArthroJet System with Cautery are available in two types, reusable and single use.

5. Intended Use

The intended use of the HydroCision ArthroJet System with Cautery is to resect damaged tissue, remove extraneous matter, and control bleeding in surgical applications of articular body cavities.

6. Comparison of Technological Characteristics

The HydroCision ArthroJet System with Cautery is a surgical device which provides cutting, tissue removal, and electrocauterization in the same tool. It is substantially equivalent in intended use and/or function to the following predicate devices: the HydroCision ArthroJet System (K982266), the Valleylab Electrosurgical Pencil (K861112)/Valleylab Electrode (K791638), and the Kirwan Suction Coagulator (K965421). It is also substantially equivalent to the ArthroCare Electrosurgery System (K963123) in that the ArthroCare unit provides all the above functions in the same unit and handpiece.

The HydroCision ArthroJet System with Cautery provides the same functions as the first predicate device, the HydroCision ArthroJet System (K982266). Both are used in arthroscopy to cut and remove tissues. They are the same device, with the exception that the HydroCision ArthroJet System with Cautery provides the additional electrocautery function using bipolar energy to cauterize small vessels that ooze during surgery. The electrocautery function and its intended use is the same as that provided by the Valleylab Electrosurgical Pencil (K861112)/Electrode (K791638) and the Kirwan Suction Coagulator (K965421).

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The mechanical action of the ArthroCare Electrosurgery System is different but it has been included as a predicate device to demonstrate the basis for a multiple function handpiece used for arthroscopic and general surgery.

7. Performance Testing

The ArthroJet System with Cautery adds a cauterization function to the original HydroCision ArthroJet System (K982266).

HydroCision Inc. ArthroJet System with Cautery complies with the following voluntary standards:

ANSI/AAMI HF18-1993
IEC 60601-2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 1999

Ms. Debbie Iampietro
Consultant
HydroCision, Inc.
220 Ballardvale Street
Wilmington, Massachusetts 01887

Re: K993009
Trade Name: HydroCision ArthoJet System with Cautery
Regulatory Class: II
Product Code: HRX
Dated: August 31, 1999
Received: September 7, 1999

Dear Ms. Iampietro:

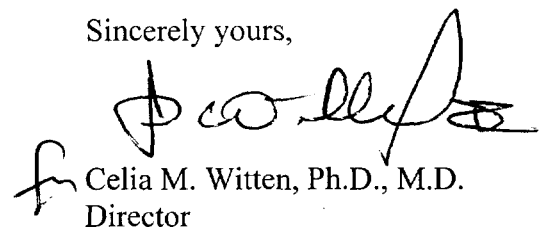
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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.

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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993009

Device Name: HydroCision ArthroJet System with Cautery

Indications For Use:

The intended use of the HydroCision ArthroJet System with Cautery is to resect damaged tissue, remove extraneous matter, and control bleeding in surgical applications of articular body cavities.

(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 K993009

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