

SEP 25 1998

510(K) SUMMARY

K982266

1. SUBMITTER:

SEP 25 1998

HydroCision, Inc.
220 Ballardvale Street
Wilmington, MA 01887
Telephone: 978-657-0020

Contact: Don Freeman, President
Date Prepared: June 17, 1998

2. DEVICE:

Arthroscopic Cutting System
Classification Name: Arthroscope and Accessories
Trade Name: HydroCision ArthroJet

3. PREDICATE DEVICE:

The predicate device used to determine substantial equivalence for the HydroCision ArthroJet was the Dyonics Articular Shaver System, marketed by Smith & Nephew Dyonics, Andover, MA

4. DEVICE DESCRIPTION:

The HydroCision ArthroJet system consists of an electric motor used to power a drive train inside a console. The drive train converts the rotational motion of a cam to a transverse motion of a plunger which in turn drives a piston contained in a disposable cartridge. The repeated motion of the piston pressurizes saline in the cartridge which is then carried through tubing to a handpiece. The handpiece delivers the high pressure saline to the joint, resulting in the cutting action of the waterjet. The result is a thin waterjet stream capable of cutting and ablating tissue which is then removed from the surgical site.

5. INTENDED USE:

The Arthrojet system is intended to resect damaged tissue and remove extraneous matter found in articular body cavities. The system may be used open or arthroscopically to resect tears and other defects, remove loose fragments, shave away debris and perform appropriate synovectomy procedures.

6. COMPARISON OF CHARACTERISTICS:

The HydroCision ArthroJet system is electrically powered and consists of a console unit, pump cartridge, tubing and handpiece. It uses a drive train to pressurize saline in a pump cartridge which is delivered to a hand piece resulting in a thin high pressure waterjet stream capable of cutting and ablating tissue, which is then removed from the site.

The Dyonics shaver is also an electrically powered unit which is used to power a hand held motor. The motor is used to exert rotational force to a disposable cutter. The cutter resects tissue by rotating at high rates of speed resulting in the tissue being cut and removed from the area.

The indications for use of the two devices are identical.

7. PERFORMANCE DATA:

The following performance data is provided in support of the substantial equivalence determination:

1. Porcine Evaluation: The ability of the ArthroJet to resect and ablate various types of tissue was demonstrated in a porcine knee.
2. In-Vivo Testing: The testing demonstrated the efficacy of the HydroCision ArthroJet in resecting rabbit menisci when compared to the predicate device. The testing confirmed that the device functions adequately to meet its intended use.
3. Bending Strength: The bending strength of the handpiece was evaluated for its ability to withstand arthroscopic applications.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 1998

D.C. Freeman, Jr. Ph.D.
President
HydroCision, Inc.
220 Ballardvale Street
Wilmington, Massachusetts 01887

Re: K982266
Trade Name: HydroCision Arthrojet System
Regulatory Class: II
Product Code: HRX
Dated: June 25, 1998
Received: June 29, 1998

Dear Dr. Freeman:

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.

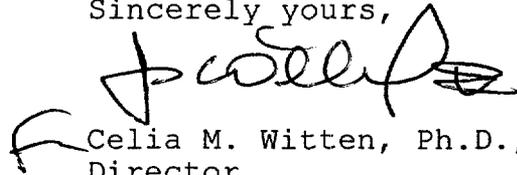
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

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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) 594-4659. 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" (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

K982266

INDICATION FOR USE

The ArthroJet system is intended to resect damaged tissue and remove extraneous matter found in articular body cavities. The system may be used open or arthroscopically to resect tears and other defects, remove loose fragments, shave away debris and perform appropriate synovectomy procedures.

Prescription Use _____
(Per 21 CFR 801.109) *X*

[Signature]

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982266