K991383

MAR 3 1 2000

HYDROCISION, INC.
100 Burtt Rd, Suite G01
Andover, MA 01810

510K Summary
HydroCision, Inc. Debridement System

1. Sponsor Name
   HydroCision, Inc
   100 Burtt Road, Suite G01
   Andover, MA 01810
   Telephone: 978 474-9300
   Contact Individual: Debbie Iampietro

2. Device Name

   Proprietary Name: HydroCision Debridement System
   Common/Usual Name: pulse lavage with sharp debridement
   Classification Name: unclassified

3. Identification of Legally Marketed Device

   The HydroCision, Inc Debridement System is substantially equivalent in intended use to the Stryker Corporation Interpulse Pulse Lavage System (K972069) in combination with sharp debridement. The intended use is also the same as the Zimmer Pulsavac Wound Debridement System in combination with sharp debridement.

   It is also substantially equivalent in design, materials and construction to its own ArthroJet System cleared under K982266.

4. Device Description

   The HydroCision Debridement System uses pressurized streams of sterile saline to lavage and clean wounds. The streams of saline simultaneously wash the tissue surface and vacuum away foreign material, including contamination and infected and necrotic tissue from the wound. The system employs two basic system components to achieve this purpose:
   - the reusable power console unit
   - the sterile, disposable pump cartridge, handpiece and tubing assembly

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5. Intended Use

The HydroCision, Inc. Debridement System is intended for wound debridement, soft tissue debridement, and cleansing of the surgical site in applications in which, in the physicians judgement, would require the use of a pulse lavage device with sharp debridement. This device is not intended to be used on burns.

6 Comparison of Technological Characteristics

The HydroCision, Inc Debridement System is substantially equivalent in intended use to the Stryker Corporation Interpulse Pulse Lavage System (K972069) in combination with sharp debridement. This device is intended for wound debridement, soft tissue debridement, and cleansing of the surgical or medical clinical site. The device helps to remove blood, tissue debris and foreign matter from the operative or wound site. The intended use is also the same as the Zimmer Pulsavac Wound Debridement System in combination with sharp debridement. It is also substantially equivalent in design, materials and construction to its own ArthroJet System cleared under K982266.

The devices have similar flow rates and power requirements. The components of each system are similar in that they each contain: a reusable power console unit, a sterile, disposable pump cartridge, a handpiece assembly, and a tubing set

6. Performance Testing

Bench testing was conducted to determine device functionality. In addition, a porcine study compared the HydroCision device to the Zimmer Puls-A-Vac II pulsatile lavage device in combination with sharp debridement. The results of this evaluation found both techniques were equally effective in clearing bacterial and particulate contamination from the wounds as examined by quantitative bacteriology and radiographic analysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2000

Ms. Debbie Iampietro
Regulatory Affairs
Hydrocision, Inc.
100 Burtt Road, Suite G01
Andover, Massachusetts 01810

Re: K991383
Trade Name: HydroCision Inc. Debridement System
Regulatory Class: II
Product Code: FQH
Dated: January 7, 2000
Received: January 10, 2000

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,

for 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

Attachment B

510(k) Number K991383

Device Name: HydroCision Inc. Debridement System

Indications For Use:

The HydroCision, Inc. Debridement System is intended for wound debridement, soft tissue debridement, and cleansing of the surgical site in applications in which, in the physicians judgement, would require the use of a pulse lavage device with sharp debridement. This device is not intended to be used on burns.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991383

Prescription Use X OR Over-The-Counter Use