HydroCision®
The Leader in Hydrosurgery™

MAY - 9 2003

HydroCision
100 Burtt Rd. Suite G01
Andover, MA 01810
Tel: 978-474-9300
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510K Summary of Safety and Effectiveness
HydroCision, Inc. General Surgery FluidJet System
April 26, 2003
K021813

1. Sponsor Name

   HydroCision, Inc
   100 Burtt Rd. Suite G01
   Andover, MA 01810
   Tel: 978-474-9300
   Contact Individual: Debbie Iampietro

2. Device Name

   Proprietary Name: HydroCision General Surgery FluidJet System
   Common/Usual Name: Surgical Instrument

   Classification Name: Surgical Instrument, AC Powered motors and accessories, Class II – General Surgery Devices
   21 CRF 878. 4820 Procode 87HWE

3. Identification of Legally Marketed Device

   The HydroCision General Surgery FluidJet System is substantially equivalent to the following devices:

   - HydroCision Debridement System, K011612
   - Xomed XPS Power Sculpt, K992855
   - Andreas Pein, GMBH, Helix HydroJet, K012464
   - ValleyLab, Force 2 Electrosurgical Generator K844403

4. Device Description

The HydroCision General Surgery FluidJet System uses a pressurized stream of sterile saline to lavage and clean wounds. The stream of saline simultaneously washes the tissue surface and vacuums 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

5. Intended Use

The intended use of the HydroCision General Surgery FluidJet System is for the tangential cutting, resection and removal of soft tissue or fluid from the body. HydroCision General Surgery FluidJet System is not intended for use in suction lipoplasty procedures.

6 Comparison of Technological Characteristics

The HydroCision, Inc General Surgery FluidJet System is identical in function and technology and design to the currently marketed HydroCision, Inc Debridement System (K011612). The components of the General Surgery FluidJet System and the Debridement systems are identical in that they each contain: a reusable power console unit, a sterile, disposable pump cartridge, a handpiece assembly, and a tubing set.

The components and mechanism of action of the HydroCision General Surgery FluidJet System and the Xomed device are different in that the Xomed unit operates on suction while the General Surgery FluidJet System operates on water energy.

The Helix HydroJet also operates on water energy but with slightly different handpieces.

7. Performance Testing

Bench testing, biocompatibility and animal testing were conducted to determine device functionality and conformance to design input requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2003

Ms. Debbie Iampietro
HydroCision, Inc.
100 Burtt Road, Suite G01
Andover, Massachusetts 01810

Re: K021813
Trade/Device Name: HydroCision General Surgery FluidJet System
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet lavage
Regulatory Class: II
Product Code: FQH
Dated: February 14, 2003
Received: February 24, 2003

Dear Ms Iampietro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

Enclosure

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510(k) Number (if known): K021813

Device Name: HydroCision General Surgery FluidJet System

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021813

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