K020688 1/2

APR 0 3 2002

HydroCision
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510K Summary of Safety and Effectiveness
February 27, 2002
HydroCision ArthroJet System with Cautery and TurboBurr
A Modification to the
HydroCision ArthroJet System with Cautery and Burr

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 ArthroJet System with Cautery and TurboBurr
   Common/Usual Name: Arthroscope and Accessories
   Classification name: Arthroscope and Accessories

3. Identification of Legally Marketed Device

   The modified HydroCision ArthroJet System with Cautery and TurboBurr is substantially equivalent in intended use to the HydroCision ArthroJet System with Cautery and Burr (K002764) and the Anspach eMax Drill (K011444).

4. Device Description

   The HydroCision ArthroJet System with Cautery and TurboBurr consists of the reusable power control unit; a sterile, disposable pump cartridge and tubing assembly; and sterile, disposable handpieces. It provides the same functions as the predicate upon which it is based. The handpiece includes the rotating burr, which is driven by a fluidjet driven rotor.

5. Intended Use

   The HydroCision ArthroJet System with Cautery and TurboBurr is indicated for orthopedic surgical procedures where the cutting and removal of soft tissue and the ablation and removal of hard tissue or bone is required, with control of bleeding during those procedures as needed. Specific functions include cutting,

ablation and shaping of soft tissue, and drilling, reaming, decorticating and smoothing of bone, cartilage and other bone related tissue in a variety of surgical procedures including open and arthroscopic spinal surgeries and small and large joint arthroscopic procedures.

6. Comparison of Technological Characteristics

Both the current and modified devices:

A. Have the same indicated use

Both are intended for resection of tissue and bone in open and arthroscopic spinal surgeries and small and large joint arthroscopic procedures.

B. Use the same fundamental scientific technology

- a reusable power console unit
- fluid jet technology
- a sterile, disposable pump cartridge and tubing assembly, and handpiece assemblies comprised of two principal components:
  - a high pressure fluid conduit with integral fluidjet nozzle
  - a low pressure collection tube.

C. The differences between the proposed HydroCision ArthroJet System with Cautery and TurboBurr and the current HydroCision ArthroJet System with Cautery and Burr (K002764) are:

- Direct fluidjet functions have been separated from the rotational functions into a variety of handpieces with slightly different tip configurations. This allows the handpieces of the modified device to be smaller than the current device, which combines direct fluidjet and rotational functions. It also allows the surgeon to select from a variety of different tip geometries to optimize access to the target tissue.
- The attachment of the handpiece to the pump cartridge and tubing assembly has been changed from a permanently affixed attachment to a quick disconnect. This allows the surgeon to easily change handpieces for different functions and optimized access to target tissue.
- The turbine drive mechanism for the burr is being modified from gear driven to direct drive, resulting in higher rotational speed of the tip and lower torque.

7. Performance Testing

Bench and cadaver 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

Hydrocision, Inc.
c/o Ms. Debbie Iampietro
QRC Consulting, Inc.
7 Tiffany Trail
Hopkinton, MA 01748

APR 0 3 2002

Re: K020688
Trade/Device Name: HydroCision ArthroJet System with Cautery and TurboBurr
Regulation Number: 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: February 27, 2002
Received: March 4, 2002

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). 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

510(k) Number (if known): K020688

Device Name: HydroCision ArthroJet System with Cautery and TurboBurr

Indications For Use:

The HydroCision ArthroJet System with Cautery and TurboBurr is indicated for orthopedic surgical procedures where the cutting and removal of soft tissue and the ablation and removal of hard tissue or bone is required, with control of bleeding during those procedures as needed. Specific functions include cutting, ablation and shaping of soft tissue, and drilling, reaming, decorticating and smoothing of bone, cartilage and other bone related tissue in a variety of surgical procedures including open and arthroscopic spinal surgeries and small and large joint arthroscopic procedures.

(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 K020688