510(k) SUMMARY for NeXtra™ arthroscopic pump and shaver system.

JAN - 7 2005

Date of submission: July 4th 2004 510k #: K041824 1/2

I. Submitter:

Owner / Operator:	Future Medical Systems, SA.
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Contact:	Patrick Janin

Official correspondent:

Company:	Future Medical Systems, Inc.
Address:	504 McCormick Drive, Glen Burnie, MD 21061
Phone:	410 761 9411 ext. 11
Fax:	410 760 9422
Contact:	Mr. Steve Janin

II. Device Names:

Classification name:	Arthroscope and Accessories
Common name:	Arthroscopic pump and shaver (debridement) system and accessories.
Proprietary name:	NeXtra™ arthroscopic pump and shaver system.

III. Classification:

Class II. Product code is HRX. This device is described in 21 C.F.R § 888.1100

IV. Predicate devices:

K954465: FMS DUO (pump and shaver), Future Medical Systems
K913028: Arthro-Flow Irrigation system (pump), Davol (BARD)
K932699: ARTHREX AR-8200 SHAVER SYSTEM (Arthrex)
K940075: SHAVER BLADE SET (Arthrex)

V. Intended use:

The NeXtra™ arthroscopic pump and shaver system is intended to provide controlled fluid distension and suction, controlled cutting, burring, shaving and abrading of bone and tissue during orthopedic procedures of the knee, shoulder, elbow, wrist, ankle, hip, small joints and temporal mandibular joint (TMJ).

VI. Device Description:

The NeXtra™ arthroscopic pump and shaver system is a dual pump system that provides inflow and outflow to and from the joint cavities during arthroscopy. It combines a built in shaver that allows the removal of bone and soft tissue during orthopedic procedures. The NeXtra™ console consists of the following components:

A power supply, housing, a motherboard, two peristaltic roller heads, three tube actuators within a mechanical housing, and a touch screen LCD. The system has a user-friendly cassette load system with an intuitive LCD touch screen. Several shaver handpiece's, sheaths, foot pedal and a remote control are available as optional features. The NeXtra™ is to be used exclusively with specific FMS tube sets.

VII. Substantial Equivalence:

The device and its accessories described in this notification are similar in intended use, design and technological characteristics as the K954465: FMS DUO (pump and shaver), Future Medical Systems, the K913028: Arthro-Flow Irrigation system (pump), Davol (BARD) and the K932699: Arthrex AR-8200 Shaver System and K940075: Shaver blade set, Arthrex.

The predicate devices and the NeXtra™ are both intended to provide inflow and outflow during arthroscopic surgery. The shaver systems are both intended to remove bone and soft tissue during arthroscopic surgery.

We believe the NeXtra™ is substantially equivalent to these predicate devices since the basic features; specifications, design and intended uses are similar. The minor differences do not raise any new issues of safety and effectiveness.

VIII. Performance Data:

The device complies with IEC 60601-1 (electrical Safety), IEC 60601-1-2 (Electromagnetic Compatibility), CE mark in accordance with the Medical Device Directive 93/42/EEC, manufactured in an ISO 9001 Version 2000 and ISO 13485 facility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2005

Mr. Patrick Janin
Manager
Future Medical Systems
265, Route de la Baronne
06640 Saint-Jeannet
France

Re: K041824
Trade/Device Name: NeXtra™ arthroscopic pump and shaver system
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: November 29, 2004
Received: December 1, 2004

Dear Mr. Janin:

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 (240) 276-0115. 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 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

Indications for Use

510(k) Number (if known): K041824

Device Name: NeXtra™ arthroscopic pump and shaver system.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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