510(K) Notification SUMMARY

K060346

SUBMITTER:

Ultrazonix DNT AB
Krossverksgatan 3
SE-216 16 Malmo Sweden

DEC 22 2006

DATE PREPARED: **December 19th , 2006**

DEVICE NAME: **Ultrazonix Spine Minimal-Invasive Disc System**

CLASSIFICATION NAME: **Electrosurgical cutting and coagulation device and accessories**

PREDICATE DEVICES: **Oratec SpineCATH, Orateac ORA-50S Auto Temp Electro Thermal Spine System, and Epicor Medical UltraCinch Tissue Ablation Device & Accessories**

Device Description:

The Ultrazonix Spine Minimal-Invasive Disc System is intended for use by professional medical personnel for coagulation and decompression of intervertebral disc material to treat symptomatic patients with annular disruption of contained herniated lumbar discs. The safety and efficacy of this device has not been established in the thoracic and cervical intervertebral regions of the spine and should not be used in those regions. The Ultrazonix Spine Minimal-Invasive Disc System is comprised of a non-disposable Control Unit, and a sterile, single-use Probe Kit. These two major component parts are described as follows:

a) Non disposable Control Unit

This contains a power supply, a high frequency-generator, an amplifier, an independent safety system and a user interface with an alphanumerical display and a key pad and a foot-operated switch. The probe and a foot-operated switch are connected to the Control Unit. High frequency induced ultrasound is emitted from the probe and controlled by means of the foot-operated switch.

b) Sterile, single-use Probe Kit, consisting of

A blunt 500 mm long stainless steel Guide Pin with a diameter of 2 mm. The Guide Pin is used as a pathfinder to navigate towards the spinal disk under fluoroscopic guidance.

A 5.3 mm Dilator which is used to prepare a canal for the Introducer. It has a conical front which ensures as little harm as possible is done to adjacent tissue and blood vessels

A 6 mm Introducer which is a thin walled, approximately 180 mm long tube with a handle to be used as a guide for the Probe. It is placed over the Dilator and when the desired position against the disk is reached the Guide Pin and the Dilator are removed and

The ultrasonic Probe is inserted into the Introducer. It consists of a thin shaft with a piezo ceramic transducer placed at the front /tip.

Predicate Devices:

There has been a device previously cleared by the FDA in the following 510(K) Notification indicated for use for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs.

Table 6.
Predicate Device(s)

Device	510(k) Document Number	Date Cleared	Indications
Oratec SpineCATH Intradiscal Catheter & Oratec ORA-50 S Auto Temp Electro Thermal Spine System & Accessories	**K974464 K993854**	**3/19/1998 12/6/1999**	**coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs**
Epicor Medical UltraCinch Tissue Ablation Device and Accessories	**K040641**	**5/5/2004**	**For the ablation of cardiac tissue during cardiac Surgery**

Technologically, both the proposed and predicate devices are substantially equivalent. Both proposed and predicate devices are electrosurgical devices which are indicated for use for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained lumbar herniated discs. Both the proposed and predicate devices utilize heat generated at the tip of the catheter / probe to deliver thermal

energy to the tissue. Both also utilize a radiopaque marking at the proximal end of the catheter/probe to position the catheter/probe under fluoroscopy. Any differences between the two devices do not raise new questions of safety and effectiveness.

Intended Use:

Ultrazonix Spine Minimal-Invasive Disc System Indications:

The Ultrazonix Spine Minimal-Invasive Disc System is intended for use by professional medical personnel for coagulation and decompression of intervertebral disc material to treat symptomatic patients with annular disruption of contained herniated lumbar discs. The safety and efficacy of this device has not been established in the thoracic and cervical intervertebral regions of the spine and should not be used in those regions.

Technological Characteristics:

Technologically, both the new device and the predicate device are the same (i.e. both are intended for use for the coagulation and decompression of lumbar disc material to treat symptomatic patients with annular disruption of contained lumbar herniated discs). Any differences between the two devices do not raise new questions of safety and effectiveness

Performance Data:

Results of in vitro and animal study evaluations show that the Ultrazonix Spine Minimal-Invasive Disc System functions as intended. Sufficient pre-clinical data has been gathered to qualify that the system is safe and efficient in coagulation and decompression of disc tissue. Current clinical experiences also show that the product is safe in coagulation and decompression of lumbar discs.

Conclusions:

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the modified device is substantially equivalent to the existing legally marketed device under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

Ultrazonix DNT AB
% International Medical Products Corp.
Jeffrey R. Shideman, Ph.D.
President
7307 Glouchester Drive
Edina, Minnesota 55435

DEC 2 2 2006

Re: K060346
Trade/Device Name: Ultrazonix Spine Minimal-Invasive Disc System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: NTB
Dated: October 18, 2006
Received: October 23, 2006

Dear Dr. Shideman:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
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): K060346

Device Name: Ultrazonix Spine Minimal-Invasive Disc System

Indications for Use:

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

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

Barbara Buelow for MCM
Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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