JUN - 1 2004

K 040919

Section 4

510(k) Summary

General Information:

Submitted by: Clarus Medical, LLC
1000 Boone Avenue North
Minneapolis, MN 55427

Contact: Tom Barthel, President
Telephone 763-525-8401
Facsimile 763-525-8656

Summary Date April 5, 2004
Device Name: 21200 Nucleotome Probe Set
Common Name: Discectomy Probe
Classification Name: Arthroscope and Accessories; 888.1100

Predicate Devices:

510(k)	*Description*	*Manufacturer*
K032473	Stryker Dekompressor™ Precutaneous Discectomy Probe	Stryker Instruments
K844131	Nucleotome	Clarus Medical, LLC*
K902778	Nucleotome II Tissue Aspiration/Cutter	Clarus Medical, LLC*
K913145	Nucleotome Tissue Aspirator/Cutter	Clarus Medical, LLC*
K914282	Nucleotome(r) II (version2) Tissue Aspiration/Cutter	Clarus Medical, LLC*
K923525	Nucleotome 3.5 mm Automated Percutaneous Lumbar	Clarus Medical, LLC*
K931109	Nucleotome E Kit	Clarus Medical, LLC*
K942987	Nucleotome L Kit	Clarus Medical, LLC*
K011454	Model 2180 Spinescope Endoscope	Clarus Medical, LLC
K040424	Model 1100 Laser Endoscopic Decompression Kit (Pending)	Clarus Medical, LLC

* *See section 11 for letter of transfer.*

Intended Use:

The Clarus Model 21200 Nucleotome Discectomy Probe is intended for use in aspiration of disc material during percutaneous discectomies in the lumbar, thoracic and cervical regions of the spine.

Device Description:

General

This 510(k) submission is a modification of the existing Nucleotome devices, previously filed as K844131, K902778, K913145, K914282, K923525, K931109, K942987 and respectively found to be substantially equivalent by the FDA on November 29, 1984; October 30, 1990; December 19, 1991; December 19, 1991, February 9, 1993; March 29, 1994; and October 30, 1995. The modifications represented by this submission, is the addition of thoracic and cervical indications.

The Nucleotome Discectomy Probe is intended to be used for decompression of the discs in the spine (lumbar, thoracic and cervical). The set consists of components necessary, as required for percutaneous surgical techniques. The Model 21200 consists of a Discectomy Probe, a guide needle, a straight cannula, with dilators, a trephine and obturator, a measuring scale, a skin marking pen, and a scalpel. A syringe with a union connector is also included to help maintain the openness of the aspiration tubing.

Construction

The Clarus Model 21200 Nucleotome Discectomy Probe, contain the same items, and are manufactured, packaged, and sterilized identically, with one exception, to the devices which have been previously filed with FDA under 510(k) applications K844131, K902778, K913145, K914282, K923525, K931109, K942987 and found to be equivalent. This exception is that the working length of the device is being shortened for cervical and/or thoracic applications. The cannulas, trocars, dilators, and trephine will likewise be changed to accommodate the working length of the device.

As with the previous sets, the main components, (the endoscope, cannulas, and dilators) are manufactured by Clarus. The other individual components have been selected to offer the user a comprehensive set of instruments for disc decompression.

The cannulas and dilators are manufactured of stainless steel with a molded plastic proximal end. The trephine (coring needle) is of similar construction as well. These materials are standard to the industry for surgical instruments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2004

Mr. Tom Barthel
President
Clarus Medical, LLC
1000 Boone Avenue North
Minneapolis, Minnesota 55427

Re: K040919
Trade/Device Name: Model 21200 Nucleotome Probe Set
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope accessory
Regulatory Class: II
Product Code: HRX
Dated: April 7, 2004
Received: April 8, 2004

Dear Mr. Barthel:

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. 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): K040919

Device Name: Model 21200 Nucleotome Probe Set

Indications for Use:

The Clarus Model 21200 Nucleotome Probe Set is indicated for use in aspiration of disc material during percutaneous discectomies in the lumbar, thoracic, and cervical regions of the spine.

Prescription Use XX (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K040919