K040424 1/2

MAY 11 2004

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 February 4, 2004

Device Name: Model 1100 Laser Endoscopic Decompression Kit

Common Name: Spinal endoscope w/ laser fiber.

Classification Name: Laser Instrument, Surgical, Powered; 878.4810

**Predicate Devices:**

| *510(k)* | *Description* | *Manufacturer* |
|---|---|---|
| K922881 | Model 1100 Laser Endoscopic Decompression Kit | Clarus Medical, LLC |
| K011454 | Model 2180 Spinescope Endoscope | Clarus Medical, LLC |
| K022610 | Model 1150 Laser Fiber | Clarus Medical, LLC |

**Intended Use:**

The Clarus Model 1100 Laser Endoscopic Decompression Kit is intended to be used on patients with contained lumbar or cervical disc herniations or bulges. This is identical, with the addition of cervical, to the predicate device, Model 1100 Laser Endoscopic Decompression Kit (K922881)

**Device Description:**

General

This 510(k) submission is a modification of the existing Clarus Model 1100 Laser Endoscopic Decompression Kit, previously filed as K922881, and found to be substantially equivalent by the FDA on November 16, 1992. The K922881 510(k) device is intended for lumbar disc decompression in the spine. The modifications, represented by this submission, is the addition of cervical indications.

The Clarus Model 1100 Laser Endoscopic Decompression Kit intended use is to be endoscopic laser decompression of discs in the spine (lumbar and cervical). The kit consists of components necessary for endoscopic laser surgery where visualization and laser surgical techniques are required. The Model 1100 consists of a deflectable endoscope with a fixed laser fiber, a flexible trocar, straight and curved cannulas with dilators, a trephine and obturator, a measuring scale, a skin marking pen, and a scalpel. The cervical LASE is identical to the Clarus Model 2180 Spinescope (previously cleared for cervical visualization, K011454) with a shorter working length and the addition of a fixed laser fiber. The fixed laser fiber is identical to Clarus Model 1150 Laser Fiber (previously cleared for cervical soft tissue, K022610).

Construction

The Clarus Model 1100 Laser Endoscopic Decompression Kit, contain the same items, and are manufactured, packaged, and sterilized identically, with one exception, to the device which have been previously filed with FDA under 510(k) application K922881 and found to be equivalent. This exception is that the working length of the device is being shortened for cervical applications. The cannulas, trocars, dilators, and trephine will likewise be changed to accommodate the working length of the device.

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

MAY 11 2004

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

Re: K040424
Trade/Device Name: Model 1100 Laser Endoscopic Decompression Kit
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 17, 2004
Received: February 18, 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

510(k) Number (if known): K 040424

Device Name: Model 1100 Laser Endoscopic Decompression Kit

Indications For Use:

The Clarus Model 1100 Laser Endoscopic Decompression Kit indicated for laser disc decompression in the lumbar and cervical regions of the spine, where the laser is used to remove inner disc material.

(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

(Optional Format 1-2-96)

510(k) Number K040424