510K Summary

FEB 18 1998

Clarus Model 2600 Neuro Endoscope

K974579

General Information

Classification	Class II
Trade Name	PercScope™
Submitter	Clarus Medical Systems, Inc. 1000 Boone Avenue North, Suite 100 Golden Valley, Minnesota 55427
Contact	Dale Sappenfield VP, Operations (612) 525-8400

Predicate Devices

- Clarus Model 2230 Neuro Endoscope by Clarus Medical
- Model 1103 Laser Endoscopic Disc Decompression Kit by Clarus Medical
- Model 2125 Endoscopic Ball Probe by Clarus Medical

Device Description

The Model 2600 Neuro Endoscope is manufactured using medical grade biocompatible materials. The basic design and materials are the same as those used in the Model 1103 Laser Endoscopic Disc Decompression Kit, the Model 2230 Neuro Endoscope, and the Model 2125 Endoscopic Ball Probe. Further, the sizes and configurations of the endoscope and accessories are equivalent as well.

The Model 2600 Neuro Endoscope is a rigid fiber optic endoscope with a molded proximal handle. The optical element of the endoscope consists of a fiber optic image bundle with a distal lens and a fiber light guide. The endoscope has a working channel and a separate fluid irrigation channel.

The light and image guides are terminated with standard connectors designed to interface with light cables and video cameras. The fluid irrigation channel is terminated with a standard Luer-Lok connector. The working channel has a proximal port to allow the passage of surgical instruments.

Intended Use

The 2600 endoscope is intended for accessing and visualizing the spinal nerve root, foramina, intervertebral disc, and the surrounding tissues of the lumbar spine. The endoscope has a working channel intended for the passage of surgical instruments indicated for use in this area. Surgical instrumentation may be used for discectomy procedures, bone and osteophyte removal, procedures associated with ruptured or herniated discs such as, retrieval of extruded disc fragments and retrieval of free fragments. The Model 2600 also has an irrigation channel for sterile fluid flush or aspiration.

Testing

Biocompatibility testing was performed on the materials used in the construction of these endoscopes. All materials passed Biocompatibility testing and are suitable for this application.

Physical testing of the product will include: dimensional inspection, weld strength testing, optical clarity, light transmittance and fluid flow rate. All testing of the product yielded acceptable results.

Summary of Substantial Equivalence

The Clarus Model 2600 Neuro Endoscopes are constructed of the same material as the Series 2200 Endoscopes, the Model 2230 Endoscopes, and Model 1103 Laser Endoscopic Disc Decompression Kit as well as other Clarus products. The sizes and configuration available along with the packaging and sterilization methods are also equivalent.

The clinical indications for use are equivalent to those for Model 2230.

Therefore, due to the similarity of materials to other Clarus devices, the test results and the equivalent indication for use to other predicate devices, Clarus believes these products do not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 1998

Mr. Dale Sappenfield
Vice President Operations
Clarus Medical Systems, Incorporated
1000 Boone Avenue North, Suite 100
Golden Valley, Minnesota 55427

Re: K974579
Trade Name: PercScope™ Model 2600
Regulatory Class: II
Product Code: HRX
Dated: December 3, 1997
Received: December 8, 1997

Dear Mr. Sappenfield:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

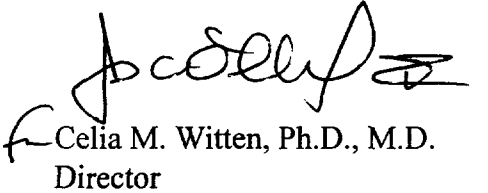
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for

devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K974579

Device Name: PercScope Model 2600

Indications For Use:

III. Device Description Information

Intended Use

The 2600 endoscope is intended for accessing and visualizing the spinal nerve roots, foramina, intervertebral disc, and the surrounding tissues of the lumbar spine. The endoscope has a working channel intended for the passage of surgical instruments indicated for use in this area. Surgical instrumentation may be used for discectomy procedures, bone, and osteophyte removal, procedures associated with ruptured or herniated discs such as, retrieval of extruded disc fragments and retrieval of free fragments. The Model 2600 also has as irrigation channel for sterile fluid flush or aspiration.

The Model 2600 Neuro Endoscope is a modification of the current Model 2230 Neuro Endoscope filled under K941188. The Model 2600 incorporates similar materials and design of the Model 2230 and the original Series 2200 Semi-rigid Endoscopes, as filed under K924554 which are manufactured of stainless steel with polycarbonate proximal handles.

Access to the nerve root area may be gained either during an open operative procedure or percutaneously. Access during an open procedure would be the same as with the Clarus Endoscopic Ball Probe filed as K922281. The percutaneous access procedure is identical to the disc access procedure used for the Model 2230. The instrumentation and technique are identical.

The Model 2600 Neuro Endoscope is packaged separately or with an accessory kit for percutaneous introduction, which includes a spinal needle, introducer cannula, and dilator. An additional kit of disposable accessories will be sold which includes the following:

- Introducer septum
- PercScope septum
- Flush tubing
- Scalpel
- Marking pen
- Plastic ruler

These accessory items are the same as identified in the Model 2230, K941188.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974579

Prescription Use X
(Per 21 CFR 801.109)

Or

Over-the Counter Use_____

(Optional Format 1-2-96)