

K980588

AUG 18 1998

510K Summary

Clarus Model 6000 Discectomy System

General Information

Classification	Class II
Trade Name	Clarus Model 6000 Discectomy System
Submitter	Clarus Medical Systems, Inc. 1000 Boone Avenue North Golden Valley, Minnesota 55427
Contact	Dale Sappenfield VP, Operations (612) 525-8400

Predicate Devices

Sofamor Danek "MED(*tm) MicroEndoscopic Discectomy System

INDICATIONS FOR USE:

The Clarus 6000 SITEtrac Discectomy System is intended for surgical use in the lumbar spine. It is supplied non-sterile and is intended for reuse. The Model 6020 Dilators and Model 6021 Retractors are intended to be used to dilate then retract the tissue in the region of the lumbar spine. This will provide an access point to apply surgical techniques through the tubular retractor under endoscopic visualization.

Device Description

The Model 6000 Discectomy System is a set of gradually increasing dilators and retractors (4.67mm to 20mm) that dilate then retract tissue in the region of the lumbar spine. This will provide an access point to apply surgical techniques through the tubular retractor under endoscopic visualization.

These reusable dilators and retractors are equivalent to those used in Sofamor Danek MED(*tm) MicroEndoscopic Discectomy System” The comparisons of these devices are shown in Table I. These retractors and dilators will be sold as a kit (See Kit Certification- Attachment F).

Cleaning and sterilization procedures for the, dilators, retractors, and spinal needle, are contained in the Directions for Use (See Attachment A).

Summary of Equivalence

The Clarus Model 6000 Discectomy System contains a set of dilators and retractors that is similar to the Sofamor Danek (K unknown) dilators and retractors in their MED MicroEndoscopic Discectomy System.

Clarus believes these products do not raise any new safety or effectiveness issues and are substantially equivalent to existing marketed devices.



AUG 18 1998

Mr. Dale Sappenfield
Vice President of Operations
Clarus Medical Systems, Inc.
1000 Boone Avenue, North
Minneapolis, Minnesota 55427

Re: K980588

Trade Name: Clarus 6000 SITETrac Discectomy System
Regulatory Class: II
Product Code: KOG
Dated: May 22, 1998
Received: May 26, 1998

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug

Mr. Dale Sappenfield Page - 2

Administration (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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-____. 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/dsma/dsmamain.html>".

Sincerely yours,

for Mark N. Milkman

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

K 980588

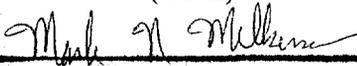
DEVICE NAME: Clarus 6000 SITetrac Discectomy System

INDICATIONS FOR USE:

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

Concurrence of CDRH , Office of Device Evaluation (ODE)

for CDRH

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 980588

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-2-96)