AUG 1 6 2000

510(k) Summary

Spinal Retractor

Surgical Dynamics
150 Glover Avenue
Norwalk, CT 06856
USA

Product Name: Spinal Retractor

The Surgical Dynamics Spinal Retractor is a hollow, rigid stainless steel instrument for use in spine surgery. The device aids in the viewing of and activity within the surgical site. Instruments that can be used through the retractor include curettes, rongeurs, drills, taps, discectomy instruments, insertion tools, and other instruments. Also, implants can be inserted using the retractor as a guide.

The Surgical Dynamics Spinal Retractor is a reusable manual surgical instrument intended to provide access to the intervertebral space by retracting tissues during open or endoscopic spine surgery.

The Surgical Dynamics Spinal Retractor was claimed to be substantially equivalent* to the Sofamor Danek Retractor included in the MED system. Information pertaining to these systems was provided in the submission.

* Any claim of substantial equivalence is made exclusively in regard to the U.S. Food and Drug Act and should not be viewed in any other light.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 6 2000

Ms. Jennifer Schuck
Regulatory Affairs Associate
United States Surgical Corporation
Surgical Dynamics
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K002008
Trade Name: Surgical Dynamics Spinal Retractor
Regulatory Class: II
Product Code: HRX, GZT
Dated: June 29, 2000
Received: July 3, 2000

Dear Ms. Schuck:

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 requirement, 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,

Donna R. Vochner

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 K002008

Device Name

Surgical Dynamics Spinal Retractor

Indications For Use

The Surgical Dynamics Spinal Retractor is a reusable manual surgical instrument intended to provide access to the intervertebral space by retracting tissues during open or endoscopic spine surgery.

(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)

Dianne R. Vachner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002008