

OCT 29 1999

Appendix 4

K992583

Summary of Safety and Effectiveness

Submitter: OMNI-TRACT Surgical Inc.
Division of Minnesota Scientific, Inc.
1100 New Brighton Blvd.
Minneapolis, MN 55413
Telephone: (612) 623-0396

Product: Classification Name: Orthopedic Manual Surgical Instrument
(21 CFR 888.4540)
Common Name: Surgical Retractor System
Trade/Proprietary Name: MASS (Micro-Access Spine System)

Substantially Equivalent Products OMNI-TRACT Surgical Retractor Systems (K842762, K853947 and K872919) and other commercially distributed devices.

Description: The device a manually adjusted retractor system. It has a single- piece retractor/access port, fiber optic light cable accessory, 2 sets of 4 varying-sized dilators and assorted manual surgical instruments whose handles conform to the shape of the retractor/access port.

Intended Use: ~~The intended use is for spinal surgery that is consistent with the working dimensions of the retractor/access port.~~

Comparison to Substantial Equivalent Products: Predicate devices have the same intended use, principle or operation, general design and materials. Differences between the new and predicate devices were subjected to bench, cleaning and sterilization testing to demonstrate that they do not affect safety and effectiveness.



OCT 29 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Cathy Miller
Regulatory Affairs Manager
Omni-Tract Surgical
Division of Minnesota Scientific, Inc.
1100 New Brighton Boulevard
Minneapolis, Minnesota 55413-1660

Re: K992583
Trade Name: Micro-Access Spine System
Regulatory Class: II
Product Code: HRX
Dated: July 27, 1999
Received: August 2, 1999

Dear Ms. Miller:

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.

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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,



for 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

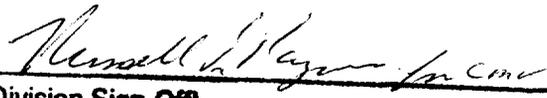
510(k) Number: K-992583

Device Name: Micro-Access Spine System

FDA's Statement of the Indications For Use for device:

The intended use is for spinal surgery that is consistent with the working dimensions of the retractor/access port.

Prescription Use X
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992583