NOV 1 0 1999

510(k) Summary

K993021

StealthStation® System - Indications Modification

Date Summary Prepared: October 26, 1999

I. **Company:** Contact: Roger N. White
Surgical Navigation Technologies
530 Compton St.
Broomfield, CO 80020
(303) 439-9709

II. **Product Trade Name:** METRx™ System
Common or usual name: Arthroscope
Classification name: Arthroscope and Accessories (HRX per 21 CFR 888.1100)

III. The above device is substantially equivalent to the Endoscopes cleared in K943356, K946087, and K955471. This submission describes a change to the indications for use and minor design changes.

IV. This submission describes a modification to the METRx™ System indications for use to provide for use of the endoscope in the cervical spine.

V. The indications for use for the METRx™ System are as follows:

The METRx™ Endoscope is Indicated for visualization of herniated disc material, visualization of the circumferential decompression of the nerve roots, and aiding in the search and removal of nucleus material. It is intended for use in the lumbar spine. The endoscope is also indicated for use in the knee, shoulder, wrist and temporomandibular joint (TMJ).

VI. The technological characteristics of the device are the same as or similar to those for the predicate devices. A comparison of technological characteristics and literature references support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 1999

Mr. Roger N. White
Group Director, Quality Systems
and Regulatory Affairs
Surgical Navigation Technologies
530 Compton Street
Broomfield, Colorado 80020

Re: K993021
Trade Name: METRx™ Endoscope
Regulatory Class: II
Product Code: HRX
Dated: September 3, 1999
Received: September 8, 1999

Dear Mr. White:

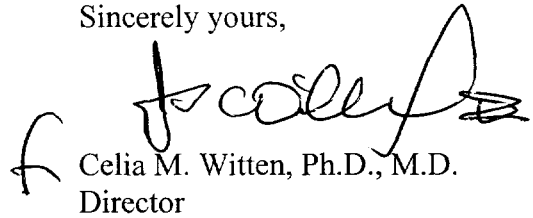
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



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): K993021

Device Name: METRx™ Endoscope – Indications Modification

Indications For Use:

The METRx™ Endoscope is Indicated for visualization of herniated disc material, visualization of the circumferential decompression of the nerve roots, and aiding in the search and removal of nucleus material. It is intended for use in the lumbar spine. The endoscope is also indicated for use in the knee, shoulder, wrist and temporomandibular joint (TMJ).

(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 K993021

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)