



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 4 1996

Myelotec, Inc.
c/o Ms. Carolann Kotula
Official Correspondent
MDI Consultants, Inc.
55 Northern Boulevard, Suite 410
Great Neck, New York 11021

Re: K960194
Trade Name: Myeloscope
Regulatory Class: II
Product Code: HRX
Dated: July 12, 1996
Received: July 16, 1996

Dear Ms. Kotula:

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.

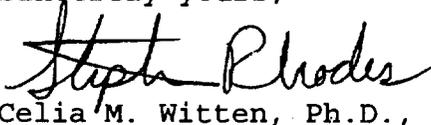
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 at (301) 443-6597.

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

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510(k) Number (if known): K960194

Device Name: Myeloscope

Indications For Use:

The Myeloscope is intended to be used by physicians for the illumination and visualization of tissues of the epidural space in the lumbar and sacral spine for the purpose of assisting in the diagnosis of disease.

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

Concurrence of CDRE, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices

510(k) Number _____

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



m d i

K960194

ATTACHMENT 1
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**510(K) SUMMARY
MYELOTec MYELOScoPE SYSTEM**

Submitter Information:

Edward J. Lortie
President
Myelotec, Inc.
1005 Alderman Drive, Suite 101
Alpharetta, GA 30202
Telephone # (770)-664-4656

510(K) Summary Prepared: June 28, 1996

Name of the Device:

Trade or Proprietary Name: Myelotec Myeloscope

Common Name: Flexible fiberoptic scope with guiding catheter

Classification Name: Arthroscope and Accessories (21 CFR Part 888.1100)

Identification of Legally Marketed Devices To Which The Submitter Claims Equivalence:

The Myelotec, Inc. Myeloscope is similar in design and/or intended use to several legally marketed flexible fiberscope endoscopes. These include the Danek Spinal Epidural Endoscope Systems (K930191) and the Ultra-Vu Endoscope Systems (K913129). These are flexible fiberoptic systems used for "micro-endoscopic" applications in small body cavities and spaces.

Description of the Subject Device:

The Myelotec Myeloscope is a flexible fiberoptic system that includes a video guided catheter that allows steering of the fiberoptic scope. The fiberoptic scope is a reusable device that is supplied non-sterile with instructions for cleaning, sterilization and re-use. The video guided catheter is a sterile, disposable device.

The optical performance characteristics of the Myelotec Myeloscope are similar to the predicate devices.

Performance testing of the video guided catheter shows that the catheter is capable of flexing the Myeloscope optics 30 degrees to the right and left for 250 cycle without damage to the tip bonds or steering mechanism.

Safety testing included biocompatibility for patient contacting materials.

Intended Use of the Subject Device

The Myeloscope is intended to be used by physicians for the illumination and visualization of tissues of the epidural space in the lumbar and sacral spine for the purpose of assisting in the diagnosis of disease.

Technological Characteristics of the Subject Device:

There are no significant technological characteristics between the Myelotec Myeloscope and the predicate devices. Optical and mechanical performance and materials are similar.

Non-clinical testing on the Myelotec Myeloscope included optical, mechanical, sterilization assurance and re-use validations.