AUG 1 1 1998

# 510(k) NOTIFICATION SUMMARY

**MYELOTEC, INC.**
**4000 NORTHFIELD WAY, SUITE 900**
**ROSWELL, GA 30076**

K980734

**CONTACT: THOMAS DUNKLE**

**PHONE: (770) 664-4656 (EXT. 20)**
**FAX: (770) 664-4363**

**DATE PREPARED: July 13, 1998**

| | |
|---|---|
| DEVICE NAME: | CATHETER |
| PROPRIETARY NAME: | MYELOTEC VIDEO GUIDED CATHETER |
| CLASS: | II |
| PANEL: | ANESTESIOLOGY |
| CLASSIFICATION NAME: | CATHETER, CONDUCTION, ANESTHESIA |
| PRODUCT CODE: | 73BSO |
| REGULATION NUMBER: | 868.5120 |
| PREDICATE DEVICE: | RACZ Tun-L-Kath 510(k) number - K954584 |

**DESCRIPTION AND INTENDED USES:**
The MYELOTEC VIDEO GUIDED CATHETER (VGC) consists of a flexible double lumen catheter, steering handle and associated ports for access to the lumens. The catheter has a built in steering mechanism that allows for guiding the soft tip through the epidural space and soft tissues for optimal access to the source of distress. Each lumen is one (1) mm in diameter. The design allows the use of a flexible fiber optic endoscope for visual examination of the area and surrounding tissues at the distal end of the catheter. This visual examination then allows the physician to diagnose the potential causes of neural distress and pain.

The port on the second lumen allows the injection of saline to expand the space and expose the source of distress for viewing and treatment. The port also facilitates the connection of syringes to deliver physician selected therapeutic agents as appropriate to their diagnosis.

**NEW INDICATIONS FOR USE:**
When used with a fiberoptic endoscope, this device can be used in the lumbar and sacral spine for observing epidural anatomy, pathology and delivery of drugs approved for epidural indications.

**EQUIVALENCE:**

COMPARISON TABLE

| ATTRIBUTE/name: | MYELOTEC VGC | RACZ Tun-L Kath |
|---|---|---|
| WHERE USED | Hospital/surgery center | Hospital/surgery center |
| SUPPLIED STERILE | YES | YES |
| SINGLE USE | YES | YES |
| INSERTION POINT | SACRAL HIATUS | SACRAL HIATUS |
| MODE OF ENTRY | 8 FR. INTRODUCER | 18 GAGE NEEDLE |
| CATHETER LENGTH | ABOUT 12 INCES | ABOUT 33 INCHES |
| LUMEN INNER DIAMETER | 0.039 INCHES | 0.021 INCHES |
| NUMBER OF LUMENS | 2 | 1 |
| ENDOSCOPE CAPABLE | YES | NO |
| STEERABLE | YES | NO |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 1 1998

Mr. Thomas A. Dunkle
Director Quality Assurance/Regulatory Affairs
Myelotec, Inc.
4000 Northfield Way, Suite 900
Roswell, Georgia 30076

Re: K980734
Trade Name: Myelotec Video Guided Catheter
Regulatory Class: II
Product Code: HRX
Dated: May 28, 1998
Received: May 29, 1998

Dear Mr. Dunkle:

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.

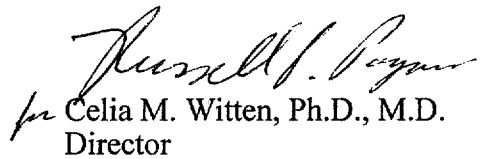
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,



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) NOTIFICATION – MYELOTEC, INC.
# ROSWELL, GA. 30076

## K980734

INTENDED USE/INDICATIONS

INTENDED USE/INDICATIONS – when used with a fiberoptic endoscope, this device can be used for observing epidural anatomy, pathology and delivery of drugs approved for epidural indications.

Russell S. Lyons for JJD

**(Division Sign-Off)**
**Division of General Restorative Devices**
**510(k) Number** K980734

**Prescription Use** ✓
**(Per 21 CFR 801.109)**