DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 1999

Mr. Donald F. Grabarz
Medimex Holfeld GMBH & CO.
c/o International Regulatory Consultants, L.C.
Mid Valley Professional Plaza
7651 S. 700 West, Suite 105
Salt Lake City, UT 84047-7101

Re: K991719
MEDIMEX Epistar/Epistar CSE Spinal/Epidural Anesthesia Kits
Regulatory Class: II (two)
Product Code: 73 CAZ
Dated: May 17, 1999
Received: May 20, 1999

Dear Mr. Grabarz:

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 legally marketed predicate 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 requirements, as set forth in the Quality System Regulation (QS) for Medical Devices:

with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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/dsma/dsmamain.html".

Sincerely yours,

Wolf Sepulveda MD for

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Revised August 13, 1999

Intended Use:

E.1 The MEDIMEX Epistar CSE kit is intended for administration of epidural anesthesia that may be combined with a spinal anesthetic. The MEDIMEX CSE epidural needle in the Epistar CSE kit I is intended for single epidural injections for epidural anesthesia, or for introduction of the MEDIMEX catheter in the CSE kit for continuous epidural anesthesia, for catheterization duration of up to 72 hours. The CSE epidural needle is also intended to allow passage of a pencil point-spinal needle into the intrathecal space to provide anesthesia immediately before or after placement of the epidural catheter. The MEDIMEX Epistar epidural kit containing the conventional epistar epidural needle, is intended only to provide epidural anesthesia by single epidural injection or by catheterization of the epidural space for up to 72 hours.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991719

Prescription Use