JUN - 1 2001

K002405
510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):

Te me na SARL
33-37, Chemin Lateral
F-93140 Bondy
France

Phone: 011- 48-50-80-83
Fax: 011-48-50-80-84

Contact Person: Virginie Siloret

Date of Summary: January 31, 2001

Trade Name: Epidural Needle

Classification Name: Needle, Conduction Anesthetic

Predicate Device:

Polymedic Spinal Needle	K940061
Reganes Epidural Needle	K854816

Device Description/ Comparison:

The Te me na Epidural Anesthesia Needles are identical in materials and manufacturing methods and to the prior cleared Te me na Polymedic Spinal Needles. This submission is for a range of additional needles similar to the Reganes Epidural Needles. This includes both Tuohy and Hustead style tips. The Temena offers one difference in a Rodeira, which is a standard Tuohy 18 AWG tip with a 17 AWG cannula.

Intended Use:

The Epidural Needle is intended to provide a mechanism for administering anesthesia to the epidural region.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2001

Mr. Arthur J. Ward
Te Me Na S.A.R.L.
c/o Regulatory and Marketing Services, Inc.
3234 Ella Lane
New Port Richey, FL 34655

Re: K002405
Te me na SARL Epidural Needle
Regulation Number: 868.5150
Regulatory Class: II (two)
Product Code: 73 BSP
Dated: March 12, 2001
Received: March 16, 2001

Dear Mr. Ward:

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. 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 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, 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) 594-4648. 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,

for

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002405

Device Name: Te me na SARL Epidural Needle

Indications For Use:

The Epidural Needle is intended to provide a mechanism for administering anesthesia to the epidural region.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002405

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

(Optional Format 1-2-96)