OCT 2 6 2004

K042375

Attachment D:

510(k) Summary

Page 1 of (2)

Manufacturer: Technomed Europe
Amerikalaan 71
6199 AE Maastricht Airport
The Netherlands

Submitted by: Technomed Europe
Amerikalaan 71
6199 AE Maastricht Airport
The Netherlands

Contact person: René Roncken
Manager Quality Assurance
Tel.: (+31) 43-408 6868
Fax: (+31) 43-408 6888
E-mail: rroncken@technomed.nl

Date: August 18, 2004

Proprietary Name: RF Injections Needles

Common/usual Name: Disposable cannula for radio frequency electrode

Classification Name: Radiofrequency lesion probe (21 CFR section 882.4725)

Substantial Equivalence:

K021942:	Radionics Pole Needles
K980430:	Radionics disposable RF Cannulae (SC-C, RFK-DB, RFK-DS)
K963577:	RSM-C, Sluijter-Mehta Cannula
K870028:	SMK Sluijter-Mehta Cannulae, RF Pole, Pole and Flexible Needles

Device description: There are four types of needles: SMK, CXE, CX and RCN

SMK is used in radiofrequency (RF) lesion procedures for the relief of pain. The device allows an injection of local anesthetic to relieve the pain of RF. A SMK-TC electrode is then place into the cannulae to create the lesion. The length of the cannula is insulated except for a section of the tip. The RF energy is then transferred from the electrode through this uninsulated portion which heats the surrounding tissue to create a lesion.

CXE is used for percutaneous facet denervations. The device consists of a shaft of hypodermic tubing, which is insulated except for 5mm at the tip. Plastic tubing and an electrical lead are unitized in a single flexible leader portion, which connects to the shaft. The lead is insulated and feed through the plastic tube. A Luer hub on the tubing allows injection of local anesthetic. The needle can be connected to a Radionics generator for stimulation and lesioning. The RF pole does not allow for temperature monitoring.

CX is used for percutaneous stimulation and injection. The design of the pole is similar to the RF pole except for the exposed tip. Only the beveled surface, 1mm, is uninsulated. The pole is intended to be connected to a stimulus generator.

RCN is used for prognostic block injections of local anesthetics or injection of contrast media. The device consists of hypodermic tubing attached PVC tubing. The needle has no electrical connection. The tubing has a Luer hub to allow the injection with a syringe at a more remote position from the needle field.

Intended Use:

A RF Injection Needle is an injection needle, which may be used either for percutaneous nerve blocks with local anesthetic solution or for radio frequency lesioning. The nerve is localized either by using electrical stimulation through the needle or by injecting contrast medium through the needle and using radiography concomitantly. The nerve may then be blocked by injecting local anesthetic or a radio frequency lesion may be made.

Technological characteristics:

The design, materials, chemical composition, packaging and other technological characteristics of the subject devices are considered to be the equivalent of the predicated devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 6 2004

Mr. René Roncken
Manager Quality Assurance
Technomed Europe
Amerikalaan 71
6199 AE Maastricht Airport
The Netherlands

Re: K042375
Trade/Device Name: RF Injection Needle
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency lesion probe
Regulatory Class: II
Product Code: GXL GXD
Dated: October 7, 2004
Received: October 12, 2004

Dear Mr. Roncken:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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 Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2. Statement Indications for Use

510(k) Number (if known): K042375

Device Name: RF Injection Needle

August 17, 2004

Indications for Use:

A RF Injection Needle is an injection needle, which may be used either for percutaneous nerve blocks with local anesthetic solution or for radiofrequency lesioning. The nerve is localized either by using electrical stimulation through the needle or by injection contrast medium through the needle and using radiography concomitantly. The nerve may then be blocked by injecting local anesthetic or a radiofrequency lesion may be made.

Prescription Use _X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___ (21 CFR 801 Subpart C)

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

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042375