SEP 1 6 2004

Section II

510(K) Summary

K041021

Company Information:

Epimed International, Inc.
141 Sal Landrio Drive
Johnstown, NY 12095
(518) 725-0209
Contact: Christopher B. Lake
Manager of RA/QA

Trade Name:

Epimed RF Introduction Cannula

Common Name:

Disposable Cannula for Radiofrequency Electrode

Product Class/Classification:

Class II

Predicate Device(s):

Radionics Disposable RF Cannulae (K980430)
Cotop International RF Cannula (K# unknown)

Description:

The Epimed RF Introduction Cannula consists of a coated stainless steel cannula with a stainless steel stylet and molded plastic hub. The cannula will be available in various lengths, gauges and tip configurations.

Intended Use:

The Epimed RF Introduction Cannula is intended for use in radiofrequency (RF) heat lesion procedures ~~for the relief of~~ pain.

Comparison to Predicate:

The Epimed RF Introduction cannula has similar physical and technical characteristics to the predicate device(s) and a similar intended use to the predicate device(s).

Non-Clinical Data:

Bench Testing performed on the Epimed RF Introduction cannula to compare performance characteristics to the predicate device(s) confirmed that the performance of the RF Introduction Cannula is similar to the predicate device(s).

Conclusion:

The testing performed and comparison to the predicate device(s) demonstrates that the Epimed RF Introduction cannula is safe and effective and is substantially equivalent to the predicate device(s).

Very truly yours,

Epimed International, Inc.

Christopher B. Lake
Manager of Quality Assurance/Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2004

Mr. Christopher B. Lake
Manager of Regulatory Affairs/Quality Assurance
Epimed International, Inc.
141 Sal Landrio Drive
Crossroads Business Park
Johnstown, New York 12095

Re: K041021
Trade/Device Name: Epimed RF Cannula
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency lesion probe
Regulatory Class: II
Product Code: GXI, GXD
Dated: September 1, 2004
Received: September 7, 2004

Dear Mr. Lake:

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 (301) 594-4659. 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,

Miriam C. Provost

for 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

Indications for Use

510(k) Number (if known): ~~unk~~ K041021

Device Name: Epimed RF Cannula

Indications for Use:

The Epimed RF Cannula is intended for use in radiofrequency (RF) heat lesion procedures for the relief of pain

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K041021