JUL 2 2 2004

Physician Industries

Manufacturing

SUMMARY OF SAFETY AND EFFECTIVENESS

K040565

SUBMITTED BY: PHYSICIAN INDUSTRIES INC.
2203 W. Alexander
Salt Lake City UT 84119
Phone: 801-886-9505, toll free 800-241-2210.

01. DEVICE NAME (Trade/common, and classification): Physician Industries' Radio-frequency Ablation Needle

    Classification: GXI; GXD

    Regulation Nos.: 882.4775; 882.4400

02. PREDICATE DEVICES:

    - Radionics' Pole Needle, K021942, found SE Sep 11, 2002);
    - Radionics' Pole Needle, K963577, found SE Nov. 21, 1996
    - See also the FDA's 510(k) database of several other products under the same classifications, also found SE, or pre-ammendment.

- DESCRIPTION: The Physician Industries Inc. needle shares major similarities with the predicate device(s), inasmuch as the configuration, material, use, labeling and safety issues remain basically unchanged. It consists of a plastic hub, insert molded over a PTFE-coated stainless steel cannula.

04. INTENDED USE: The Physician Industries' radiofrequency ablation needle is a radiofrequency needle with injection capabilities. It can be used for either 1) radiofrequency (RF) lesioning, and / or 2) percutaneous nerve blocks with a local anesthetic solution. The nerve is localized by using electrical stimulation through the needle. The nerve may then be blocked by generating an RF lesion, or by the injecting of a local anesthetic. It is to be used only under the direction of a licensed clinician.

05. SUBSTANTIAL EQUIVALENCE (SE) RATIONALE: The Physician Industries' RF Ablation Needle shares the same basic characteristics and features and, therefore, are SE to the Radionic's Pole Needles, K021942, and K963577. In addition:

    - No record of unexpected patient problems or adverse reactions were found in our review of the FDA's MAUDE, Safety Alert..., and MDR databases;

    - The device and its packaging will be tested by and independent lab for sterility, will be subjected to inspection / testing by IQC, during / after manufacture QC, and

monitored in the field by means of our CAPA system.

06. SAFETY AND EFFECIVENESS: There are no substantive differences between the device defined in this 510(k) submission and the predicate devices. It is similar to the material and manufacturing / sterilization technologies that are currently used in other similar medical devices. It was developed and documented under Physician Industries' mature Quality Management System, under the Quality System Regulation, 21 CFR Part 820, including design / change control, and is verified / validated to applicable standards / guidance documents, including vendor and our SOPs. It is designed and manufactured to be safe and effective when used as intended, under a licensed clinician's supervision.

07. The Physician Industries' Radiofrequency Ablation Needle, share similar indication for use, and characteristics and functional features, and thus are substantially equivalent to the currently marketed predicate devices, cited above.

Signed: _____ Dated: 10-21-03

Brian Baker, President
PHYSICIAN INDUSTRIES INC.
2203 W. Alexander
Salt Lake City UT 84119
Phone: 801-886-9505, toll free 800-241-2210.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 2004

Mr. Brian Baker
President
Physician Industries, Inc.
3385 West 1820 South
Salt Lake City, Utah 84104

Re: K040565
Trade/Device Name: Physician Industries' Radiofrequency Ablation Needle
Regulation Number: 21 CFR 882.4725, 21 CFR 882.4400
Regulation Name: Radiofrequency lesion probe; Radiofrequency lesion generator
Regulatory Class: II
Product Code: GXI, GXD
Dated: June 9, 2004
Received: June 15, 2004

Dear Mr. Baker:

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.

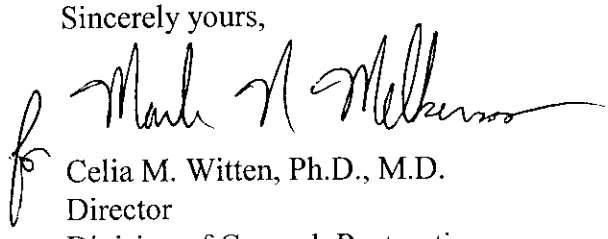
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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: **K040565**

Device Name: **Physician Industries' Radiofrequency Ablation Needle**

Indications for Use:

"The Physician Industries' Radiofrequency Ablation Needle is a single use RF (radiofrequency) needle with injection capabilities. It can be used for either 1) radiofrequency (RF) lesioning, or 2) percutaneous nerve blocks with a local anesthetic solution. The nerve is localized by using electrical stimulation through the needle. The nerve may then be blocked either by the generating an RF lesion, or by the injecting of a local anesthetic. It is to be used only under the direction of a licensed clinician."

Prescription Use **X**
(Part 21 CFR 801 Subpart D)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhem

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

510(k) Number K040565