K033739

JUL 1 2 2004

SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTED BY: PHYSICIAN INDUSTRIES INC.
3395 West 1820 South
Salt Lake City UT 84104
Phone: 801-886-9505, toll free 800-241-2210

01. DEVICE NAME ACCUMETER: Piston / control / discography syringe

Class: II (all)

Classification: IZG

Regulation Nos.: 892.1730

02. PREDICATE DEVICES:

- Balloon Inflation Syringe, cleared under K913994 (Feb 04, 1992); Similar controls, software, and materials. Different intended use.
- Digital Inflation Device (syringe), cleared under K904954 (Jan 16, 1991); Similar controls, software, and materials. Different intended use.
- Discography Kit, cleared under K960082 (Mar 21, 1996); different material same intended use.
- Discography Kit, cleared under K910503 (Oct 07, 1991), different material same intended use.

All determined to be SE.

03. DESCRIPTION: The Physician Industries' ACCUMETER.
- Polycarbonate barrel, plunger, and body, containing display software and electronics;
- Rubber plunger tip.
- Sterile (100% EtO) and non-pyrogenic (LAL).

04. INTENDED USE:

To be used for discography procedures, where the injection of contrast medium into a patient is indicated, for the purpose of viewing an area of the body (spinal disk – discography) using x-ray or photoflourographic systems, to assist in diagnosis, under the direction of a licensed clinician.

05. SUBSTANTIAL EQUIVALENCE (SE) RATIONALE: The Physician Industries' ACCUMETER shares the same general indications for use in discography as the predicates. They share the same or similar basic characteristics, materials, method of assembly / manufacture, features, and similar software of the predicates (applicable 'K' numbers listed above). In addition:
- There is no record of unexpected patient problems or adverse reactions in the FDA's MAUDE / MDR, and Safety Alert databases;

5.2. The device and its components have been tested by independent labs for EMC, and are being tested for biocompatibility in accordance with ISO10993-1:2003. The device will be subjected to incoming inspection/testing. In-process inspections will be performed during manufacturing by QC. All products will have final inspections prior to sale and will be monitored through the means of our CAPA system.

06. SAFETY AND EFFECIVENESS: There are no substantive differences between the product defined in this 510(k) submission and the predicate devices. It is similar to the technologies that are currently used in other similar medical devices. It was developed and documented under Physician Industries' Quality Management System, under the Quality System Regulation, 21 CFR Part 820, under design/change control, and is verified/validated to applicable standards/guidance documents, including software. This device family is safe and effective, when used as indicated in the application stated herein, discography, under the direction of a licensed clinician.

07. The Physician Industries ACCUMETER shares similar indications for use and characteristics and functional features, and thus is substantially equivalent to the currently marketed predicate devices, cited above.

Signed: Brian Baker Dated: July 01, 2004

Brian Baker, President
PHYSICIAN INDUSTRIES, INC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2 2004

Mr. Brian Baker
President
Physician Industries, Incorporated
3395 West 1820 South
Salt Lake City, Utah 84104

Re: K033739
Trade/Device Name: Physician Industries' Accumeter
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: May 28, 2004
Received: June 1, 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.

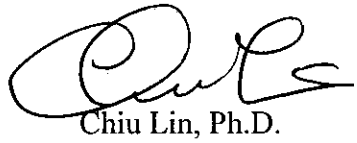
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4618. 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K033739

Device Name: Physician Industries' ~~Durameter Syringe~~ Accumeter

Indications For Use:

For use in diagnosis of herniated or otherwise diseased intervertebral disks in the human spine. This device has not been evaluated for use in vertebroplasty.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K033739