K042122

SEP 2 2 2004

510(k) Summary:
SmartInfuser PainPump™

Company Name:
Precise Medical Products Ltd.

Contact Person:

Ofer Shai
Managing Director

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Authorized US Agent:

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Trendlines America
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Leawood, Kansas 66200

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E-mail: mark@trlines.com

Date prepared: July 30, 2004

Trade Name:
SmartInfuser PainPump™

Classification name: Pump, infusion

Common/usual name: Disposable Pain Management System

Product Code: MEB

Regulation No.: 880.5725

PRECISE MEDICAL PRODUCTS LTD.

Class: II
Panel identification: General Hospital Panel

Predicate Device:
Painbuster Infusion Kit, I-Flow Corp. 20202 Widrow Dr., Lake Forest, CA 92630, cleared under 510(k) no. K982946.

Description of the device:
The device comprises of the following parts:
- SmartCatheter
- SmartInfuser set with SmartReg flow regulator (regulating set)
- Compression unit (pump)
- 100 ml or 250 ml infusion bag (empty)
- Peel-off introducer
- Medication label
- Pump label
- Carrying pouch made of synthetic cloth

The empty infusion bag is included as a back-up container. Under normal circumstances, a standard solution bag filled by a pharmacist according to the physician's prescription will be used.

Indications for Use:
The SmartInfuser PainPump is intended to provide continuous delivery of a local anesthetic through a catheter inserted directly into the surgical site for postoperative pain management.

Substantial Equivalence:
The SmartInfuser PainPump™ has the same intended use as the Painbuster Infusion Kit, cleared under 510(k) no. K9982946 and has equivalent performance characteristics. It is therefore substantially equivalent to that device.

Conclusion -
The evaluation of the SmartInfuser PainPump™ does not raise any additional concerns regarding safety and effectivity and may therefore be considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2 2004

Mr. Ofer Shay
Managing Director
Precise Medical Products Limited
P.O. Box 88
Shlomi 22832
ISRAEL

Re: K042122
Trade/Device Name: Smartinfuser PainPump™, Disposable Pain Management System
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: July 30, 2004
Received: August 6, 2004

Dear Mr. Shay:

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.

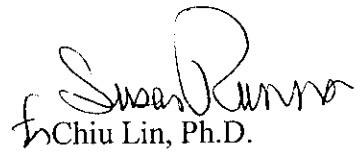
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



for 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

K042122

Indications for Use

510(k) Number (if known):

Device Name: SmartInfuser PainPump™, Disposable Pain Management System

Indications For Use:

The SmartInfuser PainPump™ is intended to provide continuous delivery of a local anesthetic through a catheter inserted directly into the surgical site for postoperative pain management.

Prescription Use √ 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)

Susan Runner

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

510(k) Number: K042122