FEB 2 2 2005

510(k) SUMMARY

K NUMBER

K042500

SPONSOR

DuoProSS Meditech Corporation
27 Sarah Drive
Farmingdale, NY 11735
Phone: 631.249.0100
Fax: 631.249.0700

SUBMITTED BY

Ferguson Medical
Consultant to DuoProSS

CLASSIFICATION NAME

Piston Syringe

CLASSIFICATION NUMBER

21 CFR 880.5680/Procode 80 FMF

PROPRIETARY DEVICE NAME

DuoProSS Syringes

DEVICE DESCRIPTION

The DuoProSS Syringes device is a sterile, single use, standard piston syringe, designed for manual use. The device is available in 1, 1 (insulin), 2, 5, 10, 20 and 60 cc/ml volumes with luer slip or luer lock configurations.

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Each syringe consists of a calibrated hollow barrel and movable plunger. At the distal end of the syringe is a male connector nozzle for fitting the female connector hub of a single lumen needle. Configurations are supplied with and without the needle already attached to the syringe.

DESIGN AND MATERIALS

The DuoProSS Syringes device consists of 3 parts or 4 parts: a barrel, a plunger, a piston and a needle. The barrel is made from polypropylene and is designed with clear graduations and figures for easy use. The piston is made from Kraton IR, a highly inert isoprene rubber. Please see List of Components and Materials table.

INTENDED USE

The DuoProSS Syringes device is intended to be used to inject fluids into, or withdraw fluids from, the body.

SUBSTANTIAL EQUIVALENCE

K020623 DuoPro Safety Syringe
K022806 Modified DuoPro Safety Syringe
K031594 1 ml Bak'Snap DuoPro Safety Syringe
K034031 10 ml Bak'Snap DuoPro Safety Syringe
K980987 Becton-Dickinson (BD) Single-Use Hypodermic and Insulin Syringes and others

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2005

DuoProSS Meditech Corporation
C/O Mr. Frank Ferguson
Official Corespondent
Ferguson Medical
12200 Academy Road NE #931
Albuquerque, New Mexico 87111

Re: K042500
Trade/Device Name: DUOPROSS SYRINGES-1ml Insulin Syringe and Duopross Syring (General USE)
Regulation Number: 880.5680
Regulation Name: Pediatric Position Holder
Regulatory Class: II
Product Code: FMF
Dated: December 28, 2004
Received: December 13, 2004

Dear Mr. Ferguson:

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.

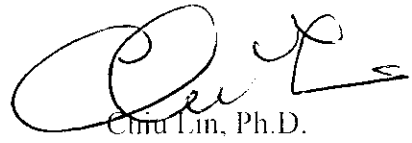
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

K042500

Indications For Use

510(k) Number (if known): **K042500**

Device Name: DUOPROSS SYRINGES – 1ml Insulin Syringe

Indications For Use:

The 1ml DuoPross Insulin Syringe is intended for the injection of insulin into the body.

Prescription Use _____ AND/OR Over-The-Counter Use XX
(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 K042500

K042500

Indications For Use

510(k) Number (If known): K042500

Device Name: DUOPROSS SYRINGES

Indications For Use:

The DuoPross Syringes device is used to inject fluids into, or withdraw fluids from, the body.

Prescription Use __XX__ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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