SEP 30 2005

K452551 (P1of2)

510(k) Summary

Submitted on behalf of:

Devon Safety Products
DBA Devon Medical Supplies
1100 First Avenue, Suite 100
King Of Prussia, PA 19406

Telephone: 1-800-431-2273
Fax: 610-768-4509

By: Barry Berler
Chief Operating Officer
1100 First Avenue, Suite 100
King of Prussia, PA 19406
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CONTACT PERSON: **Barry Berler**

DATE PREPARED: July 10, 2005

TRADE NAME: **Devon Standard Syringe and as sold under various trade names**
COMMON NAME: Piston Syringe and Hypodermic Needle

SUBSTANTIALLY EQUIVALENT TO:
The Devon Standard Syringe is substantially equivalent to:

K980181: Terumo, Disposable Hypodermic Syringe
K941657: Becton Dickinson, Insulin Syringes.
K021993: Shandong Zibo Shanchuan Medical Instrument, Co., Ltd., Piston Syringe, Hypodermic Needle: Insulin Syringe
K013293: Nipro Medical Corp., Hypodermic Needle.

DESCRIPTION of the DEVICE:
The Devon Standard Syringe is a sterile, single use, disposable syringe with attachable hypodermic needle. The Devon Standard Syringe consists of a syringe barrel, a plunger rod, piston, nozzle cap and a single lumen hypodermic needle.
The Insulin syringes are used for the injection of U100 insulin only and have scale lines in insulin units.

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INDICATIONS FOR USE:
The Devon Standard Syringe is intended for injection of fluids into, or withdrawing fluids from, parts of the body below the surface of the skin.
Syringe with plunger for general medical uses.
The Insulin syringes are intended for insulin injection.

SUMMARY of TESTING:
The Devon Standard Syringe has been shown to meet internationally recognized standards for syringe performance and labeling characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 2005

Devon Safety products, Incorporated
C/O Mr. Mark Job
Reviewer
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota, 55313

Re: K052551
Trade/Device Name: DEVON STANDARD SYRINGE, HYPODERMIC NEEDLE AND INSULIN SYRINGE
Regulation Number: 21 CFR 880.5860
Regulation Name: PISTON SYRINGE
Regulatory Class: II
Product Code: FMF and FMI
Dated: September 13, 2005
Received: September 16, 2005

Dear Mr. Job:

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

Indications for Use

510(k) Number (if known): K042551

Device Name: Devon Standard Syringe

Indications For Use:

This device is intended for injection of fluids into, or withdrawing fluids from, parts of the body below the surface of the skin.

Syringe with plunger for general medical uses.

The Insulin syringes are intended for insulin injection.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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: K042551