K052561

NOV 2 3 2005

A. Device Name

Proprietary Name: TERUMO® Micro tapered Pen Needle or other proprietary name
Common Name: Pen Needle
Classification Name: Hypodermic Single Lumen Needle (880.5570)
Product Code: 80 FMI
Classification: Class II

B. Intended Use

The TERUMO® Micro tapered pen needle is intended for use with a pen injector device for the subcutaneous injection of insulin. It is indicated for general use and for pediatric patients.

C. Device Description

The Terumo® Micro tapered pen needle is comprised of a stainless steel needle pointed at both ends with a 28gauge outer diameter at the vial end and tapers to a 33gauge outer diameter at the needle tip i.e. patient end. The tapered length is 3.5mm from the tip. The double-pointed needle is attached to a plastic hub which screws on to a compatible pen injector (not supplied with this device). It is designed to fit type A universal insulin pen injectors. The exposed patient-end needle length is 3/16" (5mm). The needle tip is covered by a colored plastic protective cap which is covered by a clear outer plastic cap. Just prior to use, the outer plastic cap is removed and retained for recapping once the injection is completed. The colored cap is then removed to expose the needle and the injection administered. After the injection, the user inserts the used needle into the open end of the outer cap so it can be safely removed from the pen injector and disposed of immediately. This pen needle device is individually packaged and sterilized. It is a disposable device intended for single use only.

D. Principle of Operation and Technology

The Terumo Micro tapered pen needle and the legally marketed BD predicate pen needle devices are operated manually.

E. Materials

The Terumo Micro tapered pen needle is comprised of a stainless steel needle, plastic hub, plastic needle inner/outer cap and plastic/paper outer packaging similar to the predicate devices.

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F. Performance

The Terumo Micro tapered pen needle was tested in accordance with ISO11608-2: 2000. Other testing included injection force and penetration resistance.

None of the data raises any new issues of safety and effectiveness. Additionally, a risk analysis was conducted and there were no new or different issues of safety and effectiveness identified for usage by adults or by children.

G. Substantial Equivalence

The Terumo 33g Micro tapered Pen Needle manufactured by Terumo Corporation in Japan is substantially equivalent to the legally marketed Becton Dickinson Ultra-fine 31g x 3/16" (5mm) pen needle cleared under K002938 and the Becton Dickinson Ultra-fine 31g x 5/16" (8mm) pen needle cleared under K955235.

Differences between the devices do not raise any significant issues of safety or effectiveness.

Terumo's statement of substantial equivalence is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended whatsoever to be the basis for a patent infringement action.

Date Prepared: September 16, 2005

Prepared By: Barbara Smith
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Prepared For: Terumo Corporation
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JAPAN

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 23 2005

Ms. Barbara Smith
Senior, Regulatory Affairs Specialist
Terumo Medical Corporation
125 Blue Ball Road
Elkton, Maryland 21921

Re: K052561
Trade/Device Name: TERUMO Micro Tapered Pen Needle
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: September 16, 2005
Received: September 22, 2005

Dear Ms. Smith:

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.

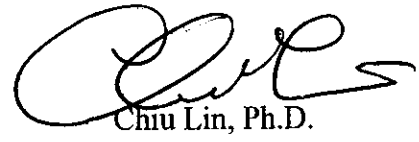
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

510(k) Number (if known): K052561

Device Name: ***TERUMO® Micro tapered Pen Needle***

Indications For Use:

The TERUMO® Micro tapered pen needle is intended for use with a pen injector device for the subcutaneous injection of insulin. It is indicated for general use and for pediatric patients.

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)

[signature]

...sion Sign-Off)
...sion of Anesthesiology, General Hospital,
...nfection Control, Dental Devices

510(k) Number: K052561