K070988

AUG 2 3 2007

ShinChang Medical Co., Ltd, South Korea
Profi Fine Pen Needle 510(k)
510(k) SUMMARY

Submitted By:

Yushin Kim, Planning Manager
#320 Gongdan-dong, Gumi City
Gyeongsangbuk-do, South Korea 730-030
Phone: 82-54-463-2400
Fax: 82-54-463-2121

Date Prepared: April 1, 2007

A. Device Name

Proprietary Name: SC Profi Fine Pen Needle (sizes varying between 31gauge x 3/16" and 28guage x 1/2")

Common Name: Pen Needle

Classification Name: Hypodermic Single Lumen Needle (880.5570)

Product Code: FMI

Classification: Class II

B. Intended Use

The SC Profi Fine Pen Needles are intended for use with insulin pen injector devices for the subcutaneous injection of insulin in the treatment of diabetes.

C. Device Description

The SC Profi Fine pen needles are comprised of a stainless steel needle pointed at both ends from 28 gauge to 31gauge. 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 lengths are 3/16"(5mm), 5/16"(8mm), and 1/2"(12.7mm). The needle tip is covered by a colored plastic protective cap, which is covered by a transparent outer plastic cap. Just prior to use, the outer plastic cap is removed and retained for recapping once the injection is complete.

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 ETO sterilized. It is a disposable device intended for single use only.

D. **Substantial Equivalence**

The SC Profi Fine pen needles manufactured by ShinChang Medical Co., Ltd in South Korea is substantially equivalent in intended use, function and basic composition to the legally marketed Becton Dickinson B-D Ultra-fine III pen needle; Model 31 gauge x 3/16", K002938, and to the Becton Dickinson B-D Ultra-Fine original Pen Needle (29 gauge x 1/2"), K031200.

E. **Technological Characteristics**

The SC Profi Fine pen needles have similar technological characteristics to the currently marketed predicated devices listed above. The SC Profi Fine pen needles meet the following standards:

ISO 11608-2, Pen-injectors for Medical Use-Part2: Needles- Requirements and Test Methods

ISO 9626, Stainless Steel Needle Tubing for Manufacture of Medical Devices

ISO 7864, Sterile Hypodermic Needles for Single Use

F. **Performance**

The SC Profi Fine pen needle was tested in accordance with ISO11608-2: 2000. Other testing reports are attached including needle pull-out, 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 23 2007

ShinChang Medical Company, Limited
C/O Ms. Jan J. Frank
Vice President
Delta Hi-Tech, Incorporated
3762 South 150 East
Salt Lake City, Utah 84115

Re: K070988
Trade/Device Name: SC Profi Fine Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: June 13, 2007
Received: August 10, 2007

Dear Ms. Frank:

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 (240) 276-3150 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

INDICATION FOR USE

510(k) Number (if known): _____

Device Name: SC Profi Fine Pen Needle

Indication For Use:

The SC Profi Fine pen needle is intended for use with insulin pen injector devices for the subcutaneous injection of insulin in the treatment of diabetes.

Prescription Use __X__ (Part 21 CFR 801 subpart D)

And/or Over-The-Counter Use___ (21 CFR 801 Subpart C)

(PLEAE 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: K070988