510(K) Summary MAR 0 2 2007

Daejin Tech Medical Manufacturing Co., Ltd.
536-70 Kumkwang-Ri KumKwang-Myun, Ansung-Si, Kyunggi-Do,
Korea
Contact person: Simon Bang, President
Tel : 82-31-671-2161
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Date prepared: November 13, 2006

1. Trade Name: Top Fine® Insulin Pen
Common Name: Insulin syringe
Classification Name: Syringe, piston, product code FMI, Regulation: 880.5570
Class of device: Class II.

2. The legally marketed device to which we are claiming equivalence [807.92(a)(3)] : Multiple: B.Braun "one.click™ needle", K033575, Terumo® Micro tapered Pen Needle K052561, BD Pen Needles K051899

3. Description of device: Top Fine® insulin pen needle consists of a sterile cap, a needle cap, and a needle hub which holds the needle. Blister paper covers the cap. The sterile cap maintains sterility the of the needle because sterile cap covers the needle hub and needle cap with blister paper sealed on the opening hole of sterile cap. The needle hub can be connected screwed onto the pen. The needle cap cover is intended to provide physical protection to the needle tube. The device is for single patient single time use. The pens come in three sizes, 29 gauge, 30 gauge, and 31 gauge. They are ETO sterilized, non toxic and non-pyrogenic.

4. Intended use: For the subcutaneous injection of insulin in the treatment of diabetes.

5. Technological characteristics: The Top Fine® Insulin Pen needles and the predicate devices have identical technological characteristics and perform the same way.

6. Performance: Both bench and clinical tests were performed. Bench testing included biocompatibility, mechanical testing, sterility testing including EO residues. Clinical testing was performed to determine adequacy of instructions for use, the range of patient population, performance characteristics, and reliability. The results were satisfactory and revealed no concerns over safety and effectiveness as compared to predicate devices. The tests demonstrated that the device is as safe, as effective, and performs in a substantially equivalent manner to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 2 2007

Daejin Tech Medical Manufacturing Company Limited
C/O Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K063466
Trade/Device Name: Top Fine® Insulin Pen
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: February 20, 2007
Received: February 23, 2007

Dear Mr. Kamm:

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

K063466

Indications for Use

510(k) Number (if known):

Device Name: Top Fine® Insulin Pen

Indications For Use:

The Top Fine® disposable sterile insulin pen needles are intended for subcutaneous injection of insulin in the treatment of diabetes..

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)

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

510(k) Number: K063466