510(K) Summary for K080904

JUN - 4 2008

Feel Tech
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Contact person: Boo Sool Kim
Date prepared: June 2, 2008

1. **Trade Name: Feel Fine Insulin Pen Needle**

2. **Common Name: Pen needle**

3. **Classification Name: Syringe, piston, product code FMI, Regulation: 880.5570**

4. **Class of device: Class II.**

5. **The legally marketed device to which we are claiming equivalence [807.92(a)(3)] : B.Braun "one.click™ needle", K033575.**

6. **Description of device: Feel Fine Insulin Pen Needle consists of a sterile cap, needle cap needle hub, which can be fixed with needle and blister paper. The sterile cap functions to maintain the sterility 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 with pen. The needle cap covers intended to provide physical protection to the needle tube. They are supplied with a sterile fluid path, (EO), non-toxic, and non pyrogenic, for single use only, disposable. The devices operate on the principles of common piston syringes.**

7. **Intended use: These disposable sterile insulin pen needles are intended for subcutaneous injection of insulin in the treatment of diabetes.**

8. **Technological characteristics: Feel Fine Insulin Pen Needles and the predicate devices have identical technological characteristics and perform the same way as common piston syringes. These needles are EO sterilized.**

9. **Performance: Bench tests were performed. Bench testing included biocompatibility, mechanical testing, sterility testing including EO residues. 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

JUN - 4 2008

Feel Tech
C/O Mr. Daniel Kamm
Principal Consultant
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K080904
Trade/Device Name: Feel Fine Insulin Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: March 28, 2008
Received: April 1, 2008

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 (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

K080904

Indications for Use

510(k) Number (if known): K080904

Device Name: Feel Fine Insulin Pen Needle

Indications For Use:

These disposable sterile insulin pen needles are intended for subcutaneous injection of insulin in the treatment of diabetes.

Prescription Us ✓ 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)

Anthony O. Watson

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

510(k) Number: K080904