JAN 10 2012

5. 510(k) Summary

[as required by 807.92(c)]

A. Applicant:

Company: Twobiens Co., Ltd.
#602, Ace High-end Tower 8, Gasan-dong, Geumcheon-gu, Seoul, 153-802, Korea
TEL. 82-2 6123 3070 Mobile. 82 10 5355 8124
http://www.twobiens.com
-Contact person: **Peter Chung** 412-687-3976
-Date: Aug 16, 2011

B. Proprietary and Established Names:

Trade Name: Fine Ject Insulin Pen Needle
Common Name: Insulin Pen Needle.
Classification Name: Needle, Hypodermic, Single Lumen
Product Code: FMI
Regulation: 880.5570
Class of device : Class II.

C. Device Description:

Fine Ject insulin pen needle consists of a Sterile Cap, needle cap needle hub, which can be fixed with needle and blister paper. The sterile cap has function to sustain sterilization of 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.
Fine Ject insulin pen needles are single use, sterile, medical devices designed to be used in conjunction with pen injectors and pen cartridges. Pen needles are used by consumers, caregivers and health care professionals. They are offered in variougauge sizes (29G, 30 G, 31G and 32G) and lengths (4mm, 5mm, 8mm and12.7mm). Fine Ject insulin pen needles are sterile (gamma irradiation sterilization), non-toxic and non-pyrogenic.
The hub has internal threads, which allows it to be screwed onto the pen-injector device. This allows the Non Patient (NP) end of the cannula to penetrate through the rubber septum of the cartridge.

D Summary of the comparison of technological characteristics

Fine Ject insulin pen needles are substantially equivalent to the intended use, function, principle of operation, and basic composition of the predicate devices.
The non-clinical testing to voluntary standards and applicable FDA guidance provide evidence Fine Ject insulin pen needle are substantially equivalent to the predicate devices in terms of safety, efficacy, and performance.
The minor differences between the Fine Ject insulin pen needle and the predicate devices, including needle gauge, needle length, and primary container material, raise no new issues of safety or effectiveness.

E. Brief discussion of non-clinical data

The Fine Ject insulin pen needles have been designed and tested to meet the requirements of voluntary standards and FDA guidance documents applicable to the subject and predicate devices.

Results of the non-clinical testing supports the conclusion of substantial equivalence of the Fine Ject insulin pen needles to the predicate devices.

Performance-Testing:

The Fine Ject insulin pen needles have been designed and successfully tested to meet the applicable requirements outlined in ISO7864, ISO 9626 and ISO 11608-2.

Biocompatibility testing

The materials of the Fine Ject insulin pen needles have successfully passed testing as outlined in ISO 10993-1 for devices categorized as External Communicating Devices, Circulating Blood,

Sterilization and Shelf-lifeTesting.

Fine Ject insulin pen needles are sterile (gamma irradiation sterilization), non-toxic and non-pyrogenic.

Shelf-life testing supports a shelf-life of 3-years after sterilization.

F. Conclusion that data demonstrates substantial equivalence

The results of above tests demonstrate that The Fine Ject insulin pen needles performs equivalent to the predicate device and is safe and effective when used as intended.

G. The legally marketed devices to which we are claiming equivalence:

Feel Fine Insulin Pen Needle. K080904
BD 32G x 4mim Pen Needle :K100005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Peter Chung
President
Twobiens Company, Limited
300 Atwood Street
Pittsburgh, Pennsylvania 15213

JAN 1 0 2012

Re: K112332
Trade/Device Name: Fine Ject Insulin Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: November 26, 2011
Received: December 14, 2011

Dear Mr. Chung:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112332

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

1. Device Name: **Fine Ject 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 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)

1/3/12

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

510(k) Number: K112332