 K110697

510(k) Summary

As Required by 21 CFR 807.92

JUL 14 2011

The assigned 510(k) Number is: ____

1. Date Prepared: Dec, 17, 2010

2. Sponsor Infromation:
Tiger Medical Products Ltd.
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3. Submission Correspondent
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4. Device Name and Classification:
1) Syringe (with/without needle)
a. Classification Name: Syringe,Piston
b. Regulation Number: 880.5860
c. Product code: FMF
d. Class: II
e. Review Panel: General Hospital

2) Insulin syringe (U-100) with fixed needle
f. Classification Name: Syringe,Piston

g. Regulation Number: 880.5860
h. Product Code: FMF
i. Class: II
j. Review Panel: General Hospital

3) Hypodermic Needle for single use
k. Classification Name: Needle, Hypodermic, Single Lumen
l. Regulation Number: 880.5570
m. Product code: FMI
n. Class: II
o. Review Panel: General Hospital

5. Predicate Device Identification:
a. **K number: K980987**
Trade Name: Becton Dickinson Single Use Hypodermic Syringes
b. **K number: K090929**
Trade Name: Sterile Insulin Syringe for single use, with fixed needle
c. **K number: K070440**
Trade Name: BD Hypoint

6. Device Description

Table-1 General Description of Applicant Devices

Device Name	Intended Use	Nozzel	Nominal Capacity / Gauge	Material	Remark
Syringe	Syringe is intended for dispensing/ administering fluids, and collecting/ sampling of fluid in medical practice.	Luer Slip	1ml、2ml、3ml、5ml、10ml、20ml、30ml、50ml	PP/PE	With or Without Needle
		Luer Lock	2ml、3ml、5ml、10ml、20ml、30ml、50ml		
Insulin Syringe	Insulin syringe (U-100) with fixed needle is a device intended for medical purposes for the manual aspiration of U-100 insulin, and for the injection of U-100 insulin into parts of the body below the surface skin.	Fixed	0.3ml、0.5ml、1ml	PP/PE	With Fixed Needle
Hypodermic Needle	Hypodermic Needle is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.	Female 6% Luer Conical Socket	16G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	SUS 304 Stainless Steel / PP	--

7. Summary of Comparison in Technological Charateristics

Through comparions between the applicant devices with the predicate devices (see comparison chart in Executive Summary), we belive the applicant devices are substantially equivalent with the predicate devices.

Technology Comparison to Predicate Device:

Item	**Syringe (with/without needle)**	**Becton Dickinson Single Use Hypodermic Syringes 510(K) #: (K980987)**
Intended Use	The Syringe is intended for dispensing/ administering fluids, and collecting/ sampling of fluid in medical practice.	The Becton Dickinson Syringes product line consists of single use disposable syringes intended for dispensing/ administering fluids, and collecting/ sampling of fluid in medical practice. Their function is mechanical.
Syringe Volume	Nominal capacity: 1,2,3,5,10,20,30,50ml (Luer Slip); 2,3,5,10,20,30,50ml (Luer Lock)	Various sizes
Needle Gauge	Various sizes	Various sizes
Needle Hub Type	Female 6% Luer	Female 6% Luer
Gradations Legibility	Legible	Legible
Lubricant Composition	Dowcorning 360 silicone (barrelinternal surface) Dowcorning 4159 silicone (needle tip)	Unknown
Barrel Transparency	Transparent and clear	Transparent and clear
Labeling and Labels	Meet FDA requirements	Meet FDA requirements
Plunger Material	PP/PE	Same
Barrel Material	PP	Same
Piston Material	Kraton IR-307 polyisoprene This compoment is not made with natural rubber latex.	Unknown
lubricant for the syringe Material	Dowcorning 360 (barrel internal surface) Dowcorning 4159 (needle tip)	Unknown
Ink on the Barrel Material	Teikuko PPE 911	Unknown
Performance	Conforms to ISO 7886-1 and ISO 7864	Conforms to ISO 7886-1 and ISO 7864
Biocompatibility	Conforms to ISO 10993	Conforms to ISO 10993
Sterility	EtO Sterilization	EtO Sterilization

Item	**Insulin syringe with fixed needle**	**Sterile Insulin Syringe for single use, with fixed needle** **510(K) #: K090929**
Intended Use	Insulin syringe (U-100) with fixed needle is a device intended for medical purposes for the manual aspiration of U-100 insulin, and for the injection of U-100 insulin into parts of the body below the surface skin.	Sterile Insulin Syringe for single use, with fixed needle is a device intended for medical purpose for the manual injection of insulin.
Specific Drug Use	U-100 Insulin	Insulin
Nominal Capacity	0.3ml、0.5ml、1ml	0.3ml、0.5ml、1ml
Needle Hub Type	Fixed	Fixed
Gradations Legibility	Legible	Legible
Lubricant Composition	Dowcorning 360 (used on internal surface of barrel) Dowcorning 4159 (used on needle tip)	Dowcorning 360 (used on internal surface of barrel) Dowcorning 4159 (used on needle tip)
Barrel Transparency	Transparent and clear	Transparent and clear
Labeling and Labels	Meets the FDA requirements	Meets the FDA requirements
Needle	SUS 304 stainless steel	304 Stainless Steel
Plunger	PE/PP	Medical Grade Polypropylene
Barrel	PP	Medical Grade Polypropylene
Piston	Kraton IR-307 polyisoprene This compoment is not made with natural rubber latex.	Santoprene TPE（Natural color）
Lubricant	Dowcorning 360 (barrel internal surface) Dowcorning 4159 (needle tip)	Polydimethlsioxane (12500 cp)
Ink on the Barrel	Teikuko PPE 911	50% SSPPNK-911 50% PPE-911
Performance	Conforms to ISO 8537	Conforms to ISO 8537
Biocompatibility	Conforms to ISO 10993	Conforms to ISO 10993
Sterility	EtO Sterilization	EtO Sterilization

Item	Hypodermic Needle for single use	BD Hypoint 510(K) #: K070440
Intended Use	The Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration	The BD HypointTM Needle is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.
Needle Gauge	Various sizes	Various sizes
Needle Hub Type	Female 6% luer conical socket	Female 6% luer conical socket
Labeling and Labels	Meet FDA requirements	Meet FDA requirements
Needle Material	SUS 304 stainless steel	Unknown
Needle Hub Material	PP	Same
Needle Sheath Material	PP	Same
Lubricant Material	Dowcorning 4159	Unknown
Performance	Conforms to ISO 7864	Conforms to ISO 7864
Biocompatibility	Conforms to ISO 10993	Conforms to ISO 10993
Sterility	EtO Sterilization	EtO Sterilization

8. Non-Clinical Test Summary

Bench tests were conducted to verify that the proposed devices meet all design specifications as are Substantially Equivalent (SE) to the predicate devices. The test results demonstrated that the proposed devices comply with the following standards:
ISO 8537:2007 Sterile single-use syringes, with or without needle, for insulin.
ISO 7886 Sterile hypodermic syringes for single use -- Part 1: Syringes for manual use
ISO 594-1:1986 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 1: General requirement
ISO 594-2: 1998 Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings
ISO 7864:1993 Sterile hypodermic needles for single use.

9. Substantially Equivalent Conclusion

The subject device and predicate device have the same classification information, intended use, sterilization specifications, performance, biocompatibility, chemical specifications, physical and mechanical specifications. Both devices meet requirements of ISO 10993, ISO 7886-1, ISO 7864 and ISO 8537. Even if there is some difference in component material (lubricant, ink, piston), we believe such difference has no adverse effect on safety and efficacy of the subject device, and we can be sure of substantial equivalence between subject device and predicate device.

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. David Wang
Tiger Medical Products, Limited
1 Huaihai Zhong Road
Liu Lin Tower, Suite 1910
Shanghai, China 200021

JUL 14 2011

Re: K110697
Trade/Device Name: Syringe (With or Without Needles), Insulin Syringe (U-100) With Fixed Needles, Hypodermic Needle for Single Use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF, FMI
Dated: June 28, 2011
Received: June 28, 2011

Dear Mr. Wang:

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,

Anthony D. Watson

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

Indications for Use

510(k) Number (if known): K110697

Device Name: Syringe (with or without needle)

Indications for Use:

The Syringe with or without needle is intended for dispensing/administering fluids, and collecting/ sampling of fluid in medical practice.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

7/13/11

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

510(k) Number: K110697

Indications for Use

510(k) Number (if known): K110697

Device Name: Insulin syringe (U-100) with fixed needle

Indications for Use:

The insulin syringe (U-100) with fixed needle is a device intended for medical purposes for the manual aspiration of U-100 insulin, and for the injection of U-100 insulin into parts of the body below the surface skin.

The proposed device of Insulin Syringe (U-100) with fixed needle is available in 0.3ml, 0.5m1, and 1ml in volume.

Prescription Use ____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use √ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
)ivision of Anesthesiology, General Hospital
nfection Control, Dental Devices

:10(k) Number: K110697

Indications for Use

510(k) Number (if known): K110697

Device Name: Hypodermic Needle for single use

Indications for Use:

The Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C Chapman 7/13/11

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

510(k) Number: K110697