K113186

APR 12 2012

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1. Submitted by : Jan /05/2012

Jiseop Jeong / Manager / Regulatory affairs
SHINA CORPORATION
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2. Device Name :

Trade Name	:	ShinaPen®
Common Names	:	Insulin pen needle
Classification Name	:	Hypodermic single lumen needle

3. Predicate Device :

UltiMed UltiCareTm Disposable Pen Needles
Manufactured by UltiMed Inc.

FlexPen Needle 32G Tip x 6mm (1/4") Disposable Needle
Manufactured by Novo Nordisk Inc.

BD 32G x 4mm Pen Needle
Manufactured by Bceton, Dickinson and Company

4. Device Description :

The ShinaPen® are designed for use with a pen injector for the subcutaneous injection of insulin. The pen needle consists of a needle, hub, and shield assembly. Blister paper covers primary container. The primary container maintains sterility the of the needle because primary container covers the hub and needle cap with blister paper sealed on the opening hole of primary container.
The needle hub can be connected screwed onto the pen. The needle shield is intended to provide physical protection to the needle tube.

The ShinaPen® are offered various gauges sizes (29G, 30G, 31G, 32G) and Lengths (4mm, 6mm, 8mm, 12.7mm). These are sterile (Eo gas sterilization), non-toxic, and non-pyrogenic. The pen needles are disposable, single use devices.

5. Intended For Use :

The ShinaPen® is designed for use with a pen injector for the subcutaneous injection of insulin.

6. Technological Characteristics :

The ShinaPen® and the predicate device have the identical technological characteristics and perform equivalently.

Device Name		Subject Device	Predicate Device #1	Predicate Device #2	Predicate Device #3
Manufacturer		SHINA CORPORATION	UltiMed Inc.	Novo Nordisk Inc.	Becton, Dickinson and company
510(k) Number		N/A	K100812	K090111	K100005
Intended for use		The ShinaPen® is designed for use with a pen injector for the subcutaneous injection of insulin.	The UltiCare Disposable Pen needles are used with insulin pen injector devices for the subcutaneous injection of insulin in the treatment of diabetes.	FlexPen needle is Intended for use with pen injector devices for the subcutaneous injection of insulin, liraglutide and somatropin	BD pen Needle is intended for use with pen injector device for subcutaneous injection of drugs, including insulin and exenatide.
Gauge		29G 30G 31G 32G	29G 31G	30G , 32G	32G
MATERIAL	Needle tube	STS304	STS304	STS304	STS304
	Hub	Polypropylene	Polypropylene	Polypropylene	Polypropylene
	Primary container	Polyethylene	Polyethylene	Polypropylene	Polypropylene
	Silicon	Poly di-methyl siloxane	Poly di-methyl siloxane	Poly di-methyl siloxane	Poly di-methyl siloxane
Sterilization		Ethylene oxide gas (SAL 10^{-6})	Ethylene oxide gas (SAL 10^{-6})	Ethylene oxide gas (SAL 10^{-6})	Gamma irradiation sterilization (SAL 10^{-6})

7. Testing

The ShinaPen® 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 tesing Supports the conlusion of substantial equivalence of

Performance Testing

ShinaPen® have been designed and successfully tested to meet the applicable requirements outlined in ISO7864, ISO9626 and ISO11608-2.

Additional performance testing to internal standards include:

Needle shield assembly force and Needle sharpness testing

Biocompatibility Testing

The material of the ShinaPen® have successfully passed testing as outlined in ISO10993-1 for devices categorized as External communicating devices, Limited exposure.

Sterilization and Shelf-life Testing

Sterilization of the ShinaPen® has been validated using the half-cycle method as outlined in ISO11135. The maximum levels of residues of ethylene oxide and ethylene chlorohydrins will not exceed the limits presented in ISO10993-7. Shelf-life testing supports a shelf-life of 3-years after sterilization

Clinical Data

No prospective clinical trials were conducted in support of this Traditional 510(k)

8. Conclusion

Based on the information provided in this premarket notification of SHINA CORPORATION. Concludes that ShinaPen® is substantially equivalent to predicate devices

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

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APR 12 2012

Re: K113186
Trade/Device Name: ShinaPen®
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: March 23, 2012
Received: April 2, 2012

Dear Mr. Jeong:

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, 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

Indication for use Statement

510(k) Number (If known) : _____

Device Name : ShinaPen®

Indication for use :

ShinaPen® is intended for use with pen injector devices for the subcutaneous injection of insulin.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 4/11/12

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

510(k) Number: K113181