DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 7, 2016

Shandong Caremed Medical Products Co., Ltd.
℅ Ms. Diana Hong
General Manager
Mid-link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K152824
Trade/Device Name: MEDT Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: January 28, 2016
Received: February 3, 2016

Dear Ms. Hong:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152824

Device Name
MEDT Pen Needle

Indications for Use *(Describe)*
The MEDT Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.
The assigned 510(k) Number: K152824

1. Date of Preparation: 03/03/2016

2. Sponsor Identification

Shandong Caremed Medical Products Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Lee Fu (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: MEDT Pen Needle
Common Name: Insulin Pen Needle

Regulatory Information
Classification Name: Needle, Hypodermic, Single Lumen;
Classification: II;
Product Code: FMI;
Regulation Number: 21 CFR 880.5570;

Review Panel: General Hospital;

Intended Use Statement:
The MEDT Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin.

Device Description

The proposed device, MEDT Pen Needle, is a single-use device, which is designed for used with a pen injector for the subcutaneous injection of insulin. It consist of three components, which are (1) needle, (2) hub and (3) inner sheath; it is sealed in a package consists of (1) a outer sheath and (2) Tyvek Paper.

5. Identification of Predicate Device(s)

510(k) Number: K133059
Product Name: Insulin Pen Needle
Manufacturer: Wenzhou Beipu Science & Technology Co., Ltd

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

<u>Physical, Mechanical and Chemical Tests performed on the proposed device</u>

- ISO 7864: 1993 Sterile hypodermic needles for single use
- ISO 9626:1991 AMD 2001 Stainless steel needle tubing for the manufacture of medical devices
- ISO 11608-2:2012 Needle-based injection systems for medical use- Requirements and test methods-Part 2: Needles

Test Item
Materials
Surface finish
Cleanliness
Limits for acidity and alkalinity
Size designation
Dimensions
Stiffness
Resistance to breakage
Resistance to corrosion

Cleanliness
Limits for acidity or alkalinity
Limits for extractable metals
Size designation
Colour coding
Needle hub
Sheath
Needle tube
Needle point
Performance
Materials
Dimensions
Determination of flow rate through the needle
Bond between hub and needle tube
Needle points
Freedom form defects
Lubrication
Dislocation of measuring point at patient end
Determination of functional compatibility with needle-based injection systems
Ease of assembly and disassembly
Sterility

Sterile Barrier Packaging Testing performed on the proposed device:

Seal Strength: ASTM F88/F88M-09 Standard test method for seal strength of flexible barrier materials

Sterilization and Shelf Life Testing performed on the proposed device:

EO residue	ISO 10993-7:2008 Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals
ECH residue	ISO 10993-7:2008 Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals
Bacteria Endotoxin Limit	USP 37-NF 32 <85> Bacterial Endotoxins Limits
Shelf Life Evaluation	Physical, Mechanical, Chemical, Package were performed on accelerated aging samples to verify the claimed shelf life of the device Sterility Test was performed per USP 38-NF 33 <71> Sterility Tests

Biocompatibility test on the proposed device:

Cytotoxicity test	ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
Intracutaneous Reactivity test	ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization
Skin Sensitization Test	ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization
Acute Systemic Toxicity Test	ISO 10993-11:2006 Biological evaluation of medical devices- Part 11: Tests for systemic toxicity
Hemolysis Test	ASTM F 756-13 Standard practice for assessment of hemolytic properties of materials
Pyrogen Test	USP 38-NF 33 <151> Pyrogen test

7. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device K152824		Predicate Device K133059	
Product Code	FMI		Same	
Regulation Number	880.5570		Same	
Intended Use	The MEDT Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin.		Same	
Configuration and material	Needle tube	Stainless Steel	Needle tube	Stainless Steel
	hub	Polypropylene	hub	Polypropylene
	Inner sheath	Polyethylene	Tube sheath	Polypropylene
	Outer sheath	Polypropylene	Hub sheath	Polypropylene
	Tyvek paper	Paper	Sealed paper	Paper
Operation mode	Manual		Same	
Needle Gauge	29G, 30G, 31G, 32G		Same	
Needle Dimension (mm)	0.23×4, 0.23×5, 0.23×6, 0.25×4, 0.25×5, 0.25×6, 0.25×8, 0.30×5, 0.30×6, 0.30×8, 0.33×10, 0.33×12		0.23×4, 0.25×4, 0.25×5,0.25×6, 0.25×8, 0.30×8, 0.30×10, 0.33×12	
Performance	Comply with ISO 7864, ISO 9626, and ISO 11608-2		Same	
Compatible pen injectors	NovoPen Echo HumaPen Luxura		Same	
Sterile	EO sterilized, SAL: 10^{-6}		Same	
Single Use	Single use		Same	
Endotoxin Limit	20 EU per product		Same	

Labeling	Conform with 21 CFR 801	Same
Biocompatibility	Conform with ISO 10993 standards	Same
Cytotoxicity	No cytotoxicity	
Intracutaneous Reactivity	No Intracutaneous reactivity	
Skin Sensitization	No significant evidence of sensitization	
Acute Systemic Toxicity	No systemic toxicity	
Hemolysis	No evidence of hemolysis	
Pyrogen	No pyrogen	

Comparison discussion:

The subject device has the same indications for use and the same principle of operation as the predicate device. Both subject and predicate devices are provided as sterile, nonpyrogenic and individually packaged.

The differences between the subject and the predicate devices include:

- The material used for Inner sheath of the subject device is Polyethylene. The material used for Tube sheath of the predicate device is Polypropylene.
- The subject and predicate devices have same needle gauges but different needle lengths. The subject device contains twelve (12) needle sizes. The predicate device contains eight (8) needle sizes.

The performance testing of the subject device met all acceptance criterial. These differences do not have impacts to product technology and performance to the subject device, and do not raise new issues of product performance.

8. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device.