August 28, 2018

Zhejiang Kindley Medical Devices Co.,Ltd
% Diana Hong
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K181069
Trade/Device Name: Disposable Insulin Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: July 20, 2018
Received: July 30, 2018

Dear Diana 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181069

Device Name
Disposable Insulin Pen Needle

Indications for Use *(Describe)*
The Disposable Insulin 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.

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Tab #7 510(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: K181069

Date of Preparation: 08/28/2018

Submitter Identification

Zhejiang kindly medical devices Co., Ltd.
No.758, 5th Binhai Road, Binhai Industrial Park, Longwan District, 325025 Wenzhou, Zhejiang Province, PRC.

Establishment Registration Number: Not yet registered

Contact Person: Yong Zhang
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Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

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Identification of Proposed Device

Trade Name: Disposable Insulin Pen Needle
Common Name: Insulin Pen Needle

Regulatory Information

Classification Name: Needle, Hypodemic, Single Lumen;
Classification: 2;
Product Code: FMI;
Regulation Number: 21 CFR 880.5570
Review Panel: General Hospital;

Identification of Predicate Device

510(k) Number: K133059
Product Name: Insulin Pen Needle

Intended Use Statement

The Disposable Insulin Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin.

Device Description

The proposed device, Disposable Insulin 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 needle tube, inner sheath, cup, hub and sealed paper. The hub can be connected screwed onto the insulin pen. The proposed device is available in following specifications

Gauge	Length (mm)	Wall
33G	Available in 4mm, 6mm	TW
32G	Available in 4mm, 6mm and 8mm	TW
31G	Available in 4mm, 6mm and 8mm	TW
30G	Available in 4mm, 6mm and 8mm	TW
29G	Available in 6mm, 8mm and 12mm	RW
28G	Available in 6mm, 8mm and 12mm	TW

Non-Clinical Test Summary

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 result comply with the related standard requirements, the test conducted on proposed devices include following

Cleanliness	Clause 4.3 of ISO 7864:2016
Limits for acidity or alkalinity	Clause 4.4 of ISO 7864:2016
Limits for extractable metals	Clause 4.5 of ISO 7864:2016
Size designation	Clause 4.6 of ISO 7864:2016
Colour coding	Clause 4.7 of ISO 7864:2016
Needle hub	Clause 4.8 of ISO 7864:2016
Needle Cap	Clause 4.9 of ISO 7864:2016
Needle tube	Clause 4.10 of ISO 7864:2016
Needle point	Clause 4.11 of ISO 7864:2016
Bond between hub and needle tube	Clause 4.12 of ISO 7864:2016
Patency of lumen	Clause 4.13 of ISO 7864:2016

Surface finish	Clause 5.2 of ISO 9626:2016
Cleanliness	Clause 5.3 of ISO 9626:2016
Limits for acidity and alkalinity	Clause 5.4 of ISO 9626:2016
Size designation	Clause 5.5 of ISO 9626:2016
Dimensions	Clause 5.6 of ISO 9626:2016
Stiffness	Clause 5.8 of ISO 9626:2016
Resistance to breakage	Clause 5.9 of ISO 9626:2016
Resistance to corrosion	Clause 5.10 of ISO 9626:2016

Material	Clause 4.1 of ISO 11608-2:2012
Dimensions	Clause 4.2 of ISO 11608-2:2012
Determination of flow rate through the needle	Clause 4.3 of ISO 11608-2:2012
Bond between hub and needle tube	Clause 4.4 of ISO 11608-2:2012
Needle points	Clause 4.5 of ISO 11608-2:2012
Freedom from defects	Clause 4.6 of ISO 11608-2:2012
Lubrication	Clause 4.7 of ISO 11608-2:2012
Dislocation of measuring point at patient end	Clause 4.8 of ISO 11608-2:2012
Determination of functional compatibility with needle-based injection systems	Clause 4.9 of ISO 11608-2:2012
Ease of assembly and disassembly	Clause 4.10 of ISO 11608-2:2012

Sterile Barrier Packaging Testing performed on the proposed device:

Seal strength	ASTM F88/F88-15
Dye penetration	ASTM F1929-15

Sterilization and Shelf Life Testing performed on the proposed device:

EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacteria Endotoxin Limit	USP <85>
Shelf Life Evaluation	Physical, Mechanical, Chemical, Package Tests were performed on aging samples to verify the claimed shelf life of the device
Sterilization validation	ANSI/AAMI/ISO 11135-1:2007

Biocompatibility Testing: Biocompatibility testing was performed according to ISO 10993 standards. The test conducted on proposed device include Cytotoxicity, Intracutaneous Reactivity, Skin Sensitization, Acute Systemic Toxicity, Pyrogen and Hemolysis Test.

Clinical Test Summary

No clinical study is included in this submission.

Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device		Predicate Device K133059	
Product Code	FMI		Same	
Regulation Number	880.5570		Same	
Intended Use	The Disposable Insulin 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	Polypropylene	Inner Sheath	Polypropylene
	Cup	Polyethylene	Cup	Polypropylene
	Sealed Paper	Paper	Sealed Paper	Paper
Needle Gauge	Available in 28G, 29G, 30G, 31G, 32G and 33G		Available in 29G, 30G, 31G and 32G	
Needle Length	Available in 4mm, 6mm, 8mm and 12mm		Available in 4mm, 5mm, 6mm, 8mm 10mm, and 12mm	
Operation mode	Manual		Same	
Sterile	EO sterilized, SAL: 10^{-6}		Same	
Single Use	Single Use		Same	
Endotoxin Limit	20EU per device		Same	
Labeling	Conform with 21 CFR 801		Same	
Biocompatibility				
Cytotoxicity	No Cytotoxicity		Conform with ISO 10993 standards	
Intracutaneous reactivity	No Irritation to Skin			
Skin Sensitization	No skin sensitization			
Acute Systemic Toxicity	No Systemic Toxicity			
Pyrogen	No pyrogen			
Hemolysis	No hemolysis			

From above comparison table, the material, needle gauge and needle length for proposed device is different from predicate device. For the difference material used in the device, biocompatibility test has been performed on proposed device and the test result can meet the requirements of ISO 10993 standards. The propose device has the additional needle gauge of 28G and 33G compared to predicate device. However, the all proposed models have been tested and the test result can meet the standard requirements. For the different in needle length, the proposed needle length can be covered by predicate device. Therefore, these differences will not raise any safety and effectiveness issues.

Substantially Equivalent (SE) Conclusion

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