DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 17, 2016

Sungshim Medicare Co., Ltd.
c/o Mr. Peter Chung
President
Plus Global
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K152334
Trade/Device Name: Sungshim Insulin Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: February 4, 2016
Received: February 10, 2016

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 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)*
K152334

Device Name
Sungshim Insulin Pen Needle

Indications for Use *(Describe)*
This product to be used with insulin injector is a single use sterile insulin pen needle to be used for injecting insulin to patient with diabetes.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

[as required by 807.92(c)]

1. Applicant

1) Company : Sungshim Medicare Co.,Ltd.
2) Address : 190, Maesil-ro, Sojeong-myeon, Sejong-si, Korea
3) Tel : 82-32-676-7066
4) Fax : 82-32-676-7063
5) Prepared date : Oct. 7, 2015
5) Contact person : Peter Chung, 412-687-3976
6) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
7) Submission date : Aug. 10, 2015
8) 510(k) number : K152334

2. Device Information

1) Trade name : Sungshim Insulin Pen Needle
2) Common name : Hypodermic single lumen needle
3) Classification name : Needle, Hypodermic, Single Lumen
4) Product code : FMI
5) Regulation number : 880.5570
6) Class of device : Class II
7) Panel : General Hospital

3. The legally marketed device to which we are claiming equivalence

K080904 Feel Fine Insulin Pen Needle

4. Device description

Sungshim insulin pen needle consist of a Sterile cap, Needle cap, Needle, Hub and Sterile paper. The Primary container and Sterile paper function to sustain sterilization of the product. The Hub can be connected with pen type insulin syringe. The Needle cap protects the Needle. This device is single use.

5. Intended Use :

This product is a single use sterile insulin pen needle intended for subcutaneous injection of insulin to patient with diabetes. It is to be used with compatible insulin injectors.

6. Performance data:

(1) Bench test were performed. Bench testing included biocompatibility, mechanical testing, sterility testing including EO residues. The tests demonstrated that the device performs in a substantially equivalent manner to the predicate device. The following bench testing is performed to demonstrate the functionality is substantially equivalent.

Test criteria : ISO 7864:1993 Sterile hypodermic needles for single use

Test item	Requirements	Results
Inner/out side and structure	When it was tested accordingly to the standard specifications for medical device-"sterile hypodermic needles for single use" clause 2, it should satisfy the requirements.	Pass
Measurement	When it was tested accordingly to the standard specifications for medical device-"sterile hypodermic needles for single use" clause 3, it should satisfy the requirements.	Pass
Elasticity test	When it was tested accordingly to the standard specifications for medical device-"sterile hypodermic needles for single use" clause 4, it should satisfy the requirements.	Pass
Draw test	When it was tested accordingly to the standard specifications for medical device-"sterile hypodermic needles for single use" clause 6, it should satisfy the requirements.	Pass
Package	When it was tested accordingly to the standard specifications for medical device-"sterile hypodermic needles for single use" clause 11, it should satisfy the requirements.	Pass
Ethylene oxide sterilization residuals	According to ISO 10993-7 ETO≤ 25ppm / ECH≤ 25ppm / EG≤250ppm	Pass
Sterility test	When it was tested accordingly to ISO 11135:2007	Pass

Extraction test			
Appearance		The sample solution shouled be colorless and transparent and there should not be foreign materials.	Pass
pH		Difference in pH≤1.5	
KM_nO_4 Reducing adents		Difference in titiers≤ 2.0ml	
Evaporating residue		Difference in extractable≤ 1.0mg	
heavy metal	Pb,Fe,Sn,Zn	Not greater than a comined total of 5mg/L of Pb, Fe, Sn and Zn	
	Cd	Shall be less than 0.1mg/L of Cd	
UV-vis spectrum		Difference in absorbance (250nm~350nm)≤ 0.1	

Compatibility testing was performed according to ISO 11608-2 and passed with the following injectors:

- Novo Nordisk A/S, Flex Pen / 3ml / Insulin sprat
- Sanofi-Aventis Deutschland GmbH. LANTUS / 3ml / Insulin glargine
- Novo Nordisk A/S, Novo Let N / 3ml / Isophane insulin

The performance tests demonstrated that Sungshim insulin pen needle performs in a substantially equivalent manner to the predicate device.

7. Predicate device comparison table

<table>
<tr><th>Manufacturer</th><th>Sungshim Medicare Co.,Ltd.</th><th>Feel Tech</th></tr>
<tr><td>510(k) No.</td><td></td><td>K080904</td></tr>
<tr><td>Indication for use</td><td>This product is a single use sterile insulin pen needle intended for subcutaneous injection of insulin to patient with diabetes. It is to be used with compatible insulin injectors.</td><td>These disposable sterile insulin pen needles are intended for subcutaneous injection of insulin in the treatment of diabetes.</td></tr>
<tr><td>Product name</td><td>Hypodermic single lumen needle</td><td>Hypodermic single lumen needle</td></tr>
<tr><td>Trade name</td><td>Sungshim Insulin Pen Needle</td><td>Feel Fine Insulin Pen Needle</td></tr>
<tr><td>Model/type</td><td>20 model codes including 29Gx4mm</td><td>Feel Fine Insulin Pen Needle-29
Feel Fine Insulin Pen Needle-30
Feel Fine Insulin Pen Needle-31</td></tr>
<tr><td>Appearance</td><td>  </td><td>  </td></tr>
<tr><td>Product configuration</td><td>Hub
Needle cap
Primary container
Needle
Sterile paper</td><td>Hub
Needle cap
Sterile cap
Needle
Sterile paper</td></tr>
<tr><td>Material</td><td><table><tr><th>Part</th><th>Material</th></tr><tr><td>Sterile cap</td><td>Polypropylene</td></tr><tr><td>Needle cap</td><td>Polyethylene</td></tr><tr><td>Needle</td><td>Stainless steel 304</td></tr><tr><td>Hub</td><td>Polypropylene</td></tr></table></td><td><table><tr><th>Part</th><th>Material</th></tr><tr><td>Sterile cap</td><td>Polypropylene</td></tr><tr><td>Needle cap</td><td>Polypropylene</td></tr><tr><td>Needle</td><td>Stainless steel 304</td></tr><tr><td>Hub</td><td>Polypropylene</td></tr></table></td></tr>
<tr><td colspan="3">Length of parts (mm)</td></tr>
<tr><td>Total length of assembly</td><td>29.8</td><td>28.8</td></tr>
<tr><td>Side length of assembly(max)</td><td>15.2</td><td>15.5</td></tr>
<tr><td>Inner diameter of sterile cap</td><td>11.2</td><td>12.95</td></tr>
<tr><td>Gauge</td><td>29G, 30G, 31G, 32G</td><td>29, 30, 31G</td></tr>
<tr><td>Length of needle</td><td>4 ㎜, 5 ㎜, 6 ㎜, 8 ㎜, 13 ㎜</td><td>5 ㎜, 8 ㎜, 12.7 ㎜</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td>Sterilization</td><td>EO Gas sterilization</td><td>EO Gas sterilization</td></tr>
<tr><td>Packagine</td><td>Sterile cap(PP)+sterile paper</td><td>Sterile cap(PP)+sterile paper</td></tr>
</table>

Although the Indications for Use is not identical to that of the predicate device, it does not change the intended use because both are single use sterile needles intended for subcutaneous injection of insulin for diabetes patients.

9. Conclusion:

Comparison results demonstrate that the specifications and performance of the device are substantially equivalent to the legally marketed predicate device.

Therefore, it is concluded that Sungshim insulin pen needle is substantially equivalent to the legally marketed predicate device.