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

July 11, 2016

Jeesung Medical Co Ltd
% Mr. Peter Chung
President
Plus Global
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K152166
Trade/Device Name: JSM Insulin Pen Needle
Regulation Number: 21 CFR 880.5770
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: May 27, 2016
Received: June 7, 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" (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 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,

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)*
K152166

Device Name
JSM Insulin Pen Needle

Indications for Use *(Describe)*
JSM insulin pen needle is intended for use with pen injector devices for the subcutaneous injection of insulin in the treatment of 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]

1. Applicant

1) Company : JeeSung Medical Co.,Ltd.
2) Address : 54, Mujini 1-gil, Daedeok-gu, Daejeon, Korea
3) Tel : 82-42-932-6061
4) Fax : 82-42-932-6063
5) Contact person : Peter Chung, 412-687-3976
6) Contact person address : 300 Atwood Street, Pittsburgh, PA, 15213, USA
7) Date of preparation : July 8, 2016
8) 510(k) number : K152166

2. Device Information

1) Trade Name : JSM Insulin Pen Needle
2) Common Name : Insulin Pen 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

JSM insulin pen needle consists of a cap, needle cap, needle, hub and paper. The cap and paper function to maintain the sterility of the needle. This device is single use and sterilized by EO gas.
The hub can be connected with pen injector. After removing the paper, the needle can be screwed on to the pen. The needle cap protects the needle.
This device has various gauge sizes (29G, 30G, 31G, 32G) and length (4mm, 5mm, 6mm, 8mm, 10mm, 12mm) The color of needle cap per needle gauge is distinguished according to the standard given by our company.

5. Indication for Use

JSM insulin pen needle is intended for use with pen injector devices for the subcutaneous injection of insulin in the treatment of diabetes.

6. Predicate device comparison table

Manufacturer	JeeSung Medical Co.,Ltd.	Feel Tech Co.,Ltd.
Element of Comparison	Submission Device	Predicate Device K080904
Indication for use	JSM insulin pen needle is intended for use with pen injector devices for the subcutaneous injection of insulin in the treatment of diabetes.	These disposable sterile insulin pen needles are intended for subcutaneous injection of insulin in the treatment of diabetes.
Trade name	JSM Insulin Pen Needle	Feel Fine Insulin Pen Needle
Model/type	JSPN-29, JSPN-30,	Feel Fine Insulin Pen Needle-29

Manufacturer		JeeSung Medical Co.,Ltd.				Feel Tech Co.,Ltd.		
		JSPN-31, JSPN-32				Feel Fine Insulin Pen Needle-30 Feel Fine Insulin Pen Needle-31		
Principle of operation		To inject insulin into body, Pen needle is connected and used with pen injector. By pen injector, the dosage of insulin is regulated. After injection, pen needle is connected with the sterile cap and unscrewed from pen injector and discarded.				To inject insulin into body, Pen needle is connected and used with pen injector. By pen injector, the dosage of insulin is regulated. After injection, pen needle is connected with the sterile cap and unscrewed from pen injector and discarded.		
Appearance								
Product configuration		Hub Needle cap Sterile cap Needle Sterile paper				Hub Needle cap Sterile cap Needle Sterile paper		
Material	Sterile cap Needle cap Needle Hub	Polypropylene Polyethylene Stainless steel 304 Polypropylene				Polypropylene Polyethylene Stainless steel 304 Polypropylene		
Gauge		29G	30G	31G	32G	29G,	30G,	31G
Length of needle tube (specified length ±1.25mm)		8 ㎜ 10 ㎜ 12 ㎜	5 ㎜ 8 ㎜ 10 ㎜ 12 ㎜	4 ㎜ 5 ㎜ 6 ㎜ 8 ㎜	4 ㎜ 5 ㎜ 6 ㎜ 8 ㎜	5 ㎜ 8 ㎜ 12.7 ㎜	5 ㎜ 8 ㎜ 12.7 ㎜	5 ㎜ 8 ㎜ 12.7 ㎜
Performances		Conforms to ISO7864, ISO 11608-2, ISO9626				Conforms to ISO7864, ISO 11608-2, ISO9626		
Biocompatibility		Conforms to ISO10993				Conforms to ISO10993		
Shelf life		3years				3years		
Sterilization		EO Gas sterilization				EO Gas sterilization		
Labeling		Meet the requirements of 21 CFR 801				Meet the requirements of 21 CFR 801		
Packaging		Sterile cap(PP)+sterile paper				Sterile cap(PP)+sterile paper		
Intended population		All ages				All Ages		

The proposed and predicate devices have the similar indications for use, principle of operation, product configuration, material, performance, biocompatibility, shelf life, sterilization. Although the indications for use are not identical, the intended uses are as both are for the subcutaneuous injection of insulin and does not raise new questions of safety or effectiveness.
The testing in conformance with ISO 11608-2, ISO 7864 and ISO 9626 provides additional evidence that the proposed device is substantially equivalent to the predicate device

The pen injectors to be used with our pen needles are FlexPen

7. Performance data:

The JSM Pen Needle has been designed and tested to meet applicable requirements of the standards listed below.

Biocompatibility Testing

No	Test identification	Test method	Test criteria	Test result
1	Cytotoxicity test	ISO10993-5 Tests for in vitro cytotoxicity, Test on extracts method	Cytotoxicity reactivity is 0	Non- cytotoxicity (Pass)
2	Hemolysis test	ISO10993-4 Tests for interactions with blood, Evaluation of hemolytic properties of medical and their components	Hemolytic index :0-2%	Hemolytic index was 0.158%. As a result, there was non-hemolytic to the extraction solution (Pass)
3	Acute systemic toxicity test	ISO10993-11 Tests for systemic toxicity, Acute systemic toxicity	No adverse clinical signs in animals and no animals lost in excess of 10% of body weight.	Non-acute systemic toxicity (Pass)
4	Skin sensitization test	ISO10993-10 Test for Irritation and sensitization, Guinea pig Maximization test (GPMT)	Non-skin hypersensitivity reaction to negative control and test substance material.	Non-skin hypersensitivity reaction (Pass)
5	Pyrogen Test	ISO 10993 Test for systemic, Annex(F) Information on material-mediated pyrogens	No animal show an individual temperature rise of 0.5℃ or above its respective control temperature.	Non-pyrogenicity (Pass)
6	Intracutaneous reactivity test	ISO 10993-10 Test for irritation and skin sensitization, Animal Intracutaneous(intradermal) reactivity Test.	The calculated final test sample scores of polar and non-polar extract is 0.0	Non-intracutaneous (Pass)

Testing Performance to ISO 7864 (1993)

	Test items	Criteria and Result summary
1	Inner/outside and structure	No scratch, no crack, smooth, no foreign materials, sharped needle edge, glycerin untinged, no lubricant on the surface Passed
	Measurement	Outside diameter of needle : 0.267mm for criterial 0.254-0.267 Length of needle : 7.6mm for criteria 8(+1/-2) Passed
	Elasticity test	Fix A point randomly and bend 12° with weight and 1 minutes at B point Needle returned after remove weight Passed
	Draw test	Pulled in the direction of the needle axis by minimum force (22N) The union of the hub and needle tube was not broken Passed

Testing Performance to ISO 11608-2 (2012) and ISO 9626 (1991)

- The pen injectors tested under 11608-2 : FlexPen

<table>
<tr><th></th><th>Test items</th><th>Criteria and Result summary</th></tr>
<tr><td rowspan="6">1</td><td>Flow rate testing</td><td>
<table>
<tr><td>Model code</td><td>29Gx8mm</td><td>29Gx10mm</td><td>29Gx12mm</td><td></td></tr>
<tr><td>Average</td><td>8.2414mL/min</td><td>8.1687mL/min</td><td>7.8848mL/min</td><td></td></tr>
<tr><td>Model code</td><td>30Gx5mm</td><td>30Gx8mm</td><td>30Gx10mm</td><td>30Gx12mm</td></tr>
<tr><td>Average</td><td>6.1566mL/min</td><td>6.1154mL/min</td><td>5.8387mL/min</td><td>5.738mL/min</td></tr>
<tr><td>Model code</td><td>31Gx4mm</td><td>31Gx5mm</td><td>31Gx6mm</td><td>31Gx8mm</td></tr>
<tr><td>Average</td><td>4.298mL/min</td><td>4.250mL/min</td><td>4.162mL/min</td><td>4.149mL/min</td></tr>
<tr><td>Model code</td><td>32Gx4mm</td><td>32Gx5mm</td><td>32Gx6mm</td><td>32Gx8mm</td></tr>
<tr><td>Average</td><td>4.189 mL/min</td><td>4.216 mL/min</td><td>4.135 mL/min</td><td>4.094 mL/min</td></tr>
</table>
The calculation for flow rate is as above.
Passed</td></tr>
<tr><td>Bond between hub and needle tube testing</td><td>The force min. (N) for nominal outside diameter of needle (29G, 30G, 31G, 32G) is 22 N.
The union of the hub and needle tube was not broken per each gauge by the minimum force (22N)
Passed</td></tr>
<tr><td>Needle point testing</td><td>When examined under a magnification of x2.5, needle points shall appear sharp and free from feather edges, burrs and hooks.
The needle points per each gauge appeared sharp and free from feather edges, burrs and hooks.
Passed</td></tr>
<tr><td>Freedom from defects</td><td>When examined by normal or corrected vision, the needle tube shall appear straight and of regular cross-section and wall thickness.
The needle tube per each gauge appeared straight and regular cross-section and wall thickness.
Passed</td></tr>
<tr><td>Lubrication testing</td><td>If the hypodermic needle tube is lubricated, the lubricant shall not be visible, under or corrected vision, as droplets of fluid on the outside or inside surfaces of the needle tube.
The lubricant was not visible, under or corrected vision, as droplets of fluid on the outside or inside surfaces of the needle tube.
Passed</td></tr>
<tr><td>Dislocation of measuring point at patient end</td><td>
<table>
<tr><td>Patient-end needle length, l1, mm</td><td>Maximum allowable dislocation Dmax , mm</td></tr>
<tr><td>8</td><td>0,9</td></tr>
<tr><td>12</td><td>1,1</td></tr>
<tr><td>16</td><td>1,4</td></tr>
<tr><td>Others</td><td>0,07 x/1 + 0,3</td></tr>
</table>
For 12mm, 10mm, 8mm, 6mm, 5mm, 4mm, the test is performed and the test result was passed.</td></tr>
<tr><td>Needle hub-assembly testing</td><td>The needle assembly torque values shall all be within the range of 0.06Nm to 0.080Nm. The needle assembly torque values is 0.070Nm
Passed</td></tr>
<tr><td>Needle dose accuracy testing</td><td>The following two conditions shall be met:
$\bar{S}+(k\times S_{sd})\le UL$ and $\bar{S}-(k\times S_{sd})\ge LL$
The two conditions were met
Passed</td></tr>
</table>

	Needle hub torque removal testing	The needle hub removal torque shall be less than 0.1000Nm. The needle hub removal torque is 0.071Nm Passed
2	Inner/outside and structure	No scratch, no crack, smooth, no foreign materials, sharped needle edge, glycerin untinged, no lubricant on the surface Passed
	Dimension	Needle outside diameter, Needle length, Needle cap Inner diameter 29G, 30G, 31G, 32G Passed
	Flexural strength	When the needle is bended to 90° the center of the cannula according to the radius of curvature of 5mm radius, it should not be broken Passed
	Elasticity test	Fix A point randomly and bend 12° with weight and 1 minutes at B point Needle returned after remove weight Passed
	Draw test	Pulled in the direction of the needle axis by minimum force (22N) The union of the hub and needle tube was not broken Passed

8. Conclusion

Based on the comparison and analysis above, the JSM Pen Needle has the same intended use, technological characteristics, materials of construction and performance specifications as the predicate device. The subject device is determined to be Substantially Equivalent (SE) to the predicate device