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 12, 2016

Sung Shim Medicare Co., Ltd.
c/o Mr. Peter Chung
Plus Global
300 Atwood St.
Pittsburgh, Pennsylvania 15213

Re: K152803
Trade/Device Name: SUNGSHIM® Sterile Single Use Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: April 14, 2016
Received: April 20, 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)*
K152803

Device Name
SUNGSHIM® Sterile single use Insulin Syringe

Indications for Use *(Describe)*
SUNGSHIM® Sterile single use Insulin Syringe is hypodermic insulin syringe for subcutaneous injection of U-100 insulin. (Unit scale : U-100)

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
(K152803)
[as required by 807.92(c)]

1. Applicant

1) Company : Sung Shim 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 : July 12, 2016
6) Contact person : Peter Chung, 412-687-3976
7) Contact person address : 300 Atwood Street, Pittsburgh, PA, 15213, USA

2. Device Information

1) Trade name : SUNGSHIM® Sterile single use Insulin Syringe
2) Common name : Syringe, piston
3) Classification name : Piston syringe
4) Product code : FMF
5) Regulation number : 880.5860
6) Class of device : Class II
7) Panel : General Hospital
8) Model codes : Insulin Syringe 0.5ml/cc, Insulin Syringe 1ml/cc

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

K070917 Feel-ject Insulin Syringe

4. Device description

SUNGSHIM® Sterile single use Insulin Syringe is a disposable, single use syringe which consists of a calibrated hollow barrel, plunger, gasket, cap and fixed needle. The needle is a fixed and the needle cap is intended to provide physical protection to the needle. The cap is color coded orange for U-100 insulin, same as equivalent insulin syringes. The SUNGSHIM Sterile single use Insulin Syringe is available in 0.5ml/cc and 1ml/cc sizes in gauges 28g to 31g.

5. Intended Use :

SUNGSHIM® Sterile single use Insulin Syringe is hypodermic insulin syringe for subcutaneous injection of U-100 insulin. (Unit scale : U-100)

6. Performance data:

(1) Bench test
Test standard : ISO 8537:2007 Sterile single-use syringes, with or without needle, for insulin

(2) Particulate matter in injections
Test standard : USP <788>
Test item : Particulate matter in injections

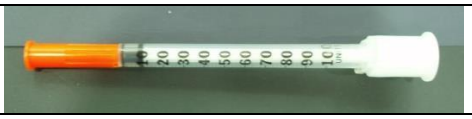
(3) Biocompatibility
Category : External communicating device
Contact : Blood path, indirect
Contact duration : A-limited (≤24h)

Test standard : ISO 10993-1, ISO 10993-4, ISO 10993-5, ISO 10993-10, ISO 10993-11, USP 39<85>

Test item : Cytotoxicity, In vitro hemolysis, Acute systemic toxicity, Skin sensitization, Intracutaneous reactivity, Endotoxin

The performance tests demonstrated that SUNGSHIM® Sterile single-use Insulin Syringe is as safe, as effective and performs in a substantially equivalent manner to the predicate device.

7. Predicate device comparison table

Manufacturer	Sung Shim Medicare Co.,Ltd.	Feel Tech
510(k) No.	K152803	K070917
Indication for use	SUNGSHIM® Sterile single use Insulin Syringe is hypodermic insulin syringe for subcutaneous injection of U-100 insulin. (Unit scale : U-100)	The Feel-ject disposable sterile insulin syringes are intended for injection of U100 insulin only.
Product name	Syringe, piston	Syringe, piston
Trade name	SUNGSHIM® Sterile single use Insulin Syringe	Feel-ject Insulin syringe
Model/type	Insulin syringe 0.5ml/cc Insulin syringe 1ml/cc	FIS-1001 1.0ml FIS-0502 0.5ml
Appearance		
Product configuration	Barrel Plunger Cap Gasket Needle	Barrel Plunger Cap Gasket Needle
Material	**Part** / **Material** Barrel / Polypropylene Plunger / Polypropylene Cap / Polyethylene Gasket / Rubber Needle / Stainless steel STS304	**Part** / **Material** Barrel / Polypropylene Plunger / Polypropylene Cap / Polyethylene Gasket / Rubber Needle / Stainless steel STS 304
Length of parts (mm) : 1.0mL		
Total length of assembly	118.2±2	116±2
Side length of assembly(max)	19.2±1	19.2±1
Inner diameter of barrel	4.74±0.3	4.7±0.3
Out diameter of barrel	7.0±0.3	6.6±0.3
Scale of syringe	1mL	1mL
Gauge	28G, 29G, 30G, 31G	28G, 29, 30, 31G
Length of needle	8 ㎜, 12.7 ㎜	5 ㎜, 8 ㎜, 12.7 ㎜
Sterilization	EO Gas sterilization	EO Gas sterilization

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 insulin syringes intended for the injection of U-100 insulin.

8. Conclusion:

The materials, performance and features of both the subject device and the predicate device are considered to be substantially equivalent.