May 12, 2020

POONGLIM Pharmatech Inc.
% Peter Chung
President
Plus Global
300 Atwood
Pittsburgh, Pennsylvania 15213

Re: K192222
Trade/Device Name: EZ-Inject Single Use Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: March 27, 2020
Received: April 13, 2020

Dear Peter 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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For CAPT Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K192222

Device Name
EZ-Inject Single use Needle

Indications for Use *(Describe)*
This device is intended for use to inject fluids into or withdraw fluids from parts of the body below the surface of the skin

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.

510(k) Summary

[as required by 807.92(c)]

1. Applicant

1) Company: POONGLIM Pharmatech Inc.
2) Address: 21, Jayumuyeok 1-gil, Gunsan-si, Jeollabuk-do, Korea
3) Tel : 82-63-451-8141
4) Fax : 82-63-451-8145
5) Prepared date : July 11, 2019
6) Contact person : Peter Chung, 412-512-8802
7) Contact person address : 300 Atwood Street, Pittsburgh, PA, 15213, USA
8) Submission date: August 11, 2017
9) Prior related submission : K172483

2. Device Information

1) Trade name : EZ-Inject Single use Needle
2) Common name : Single-use needle, hypodermic 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
8) Model/type Name : 159 model codes including Y18-13
9) List of models : Y (53 models), I (53 models), L (53 models)

Y	18-13	18-25	18-30	18-40	19-13	19-25	19-30	19-40
	21-13	21-25	21-30	21-40	22-13	22-25	22-30	22-40
	23-13	23-16	23-25	23-30	25-13	25-16	25-25	25-30
	26-13	26-16	26-25	27-13	27-16	27-25	29-08	29-13
	29-16	30-04	30-08	30-13	30-16	31-04	31-06	31-08
	31-13	32-04	32-06	32-08	32-13	33-04	33-06	33-08
	33-13	34-04	34-06	34-08	34-13			
I	18-13	18-25	18-30	18-40	19-13	19-25	19-30	19-40
	21-13	21-25	21-30	21-40	22-13	22-25	22-30	22-40
	23-13	23-16	23-25	23-30	25-13	25-16	25-25	25-30
	26-13	26-16	26-25	27-13	27-16	27-25	29-08	29-13
	29-16	30-04	30-08	30-13	30-16	31-04	31-06	31-08
	31-13	32-04	32-06	32-08	32-13	33-04	33-06	33-08
	33-13	34-04	34-06	34-08	34-13			
L	18-13	18-25	18-30	18-40	19-13	19-25	19-30	19-40
	21-13	21-25	21-30	21-40	22-13	22-25	22-30	22-40
	23-13	23-16	23-25	23-30	25-13	25-16	25-25	25-30
	26-13	26-16	26-25	27-13	27-16	27-25	29-08	29-13
	29-16	30-04	30-08	30-13	30-16	31-04	31-06	31-08
	31-13	32-04	32-06	32-08	32-13	33-04	33-06	33-08
	33-13	34-04	34-06	34-08	34-13			

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

K172483, KOPAC Sterile Needle

4. Device description

The device consists of a metal tube that is beveled at one end and at the other end join to a female connector (hub). The needle cap covers intended to provide physical protection to the needle tube. This product is packed by blister paper and sterilized by E.O. gas.

Needle gauge : 18, 19, 21, 22, 23, 25, 26, 27, 29, 30, 31, 32, 33, 34G
Needle length : 4, 6, 8, 13, 16, 25, 30, 40 mm
Wall thickness
RW (Regular-Wall) : 18G, 19G, 21G, 22G, 23G, 25G, 26G, 27G, 29G, 30G, 31G, 32G, 33G, 34G
TW (Thin Wall) : 18G, 19G, 21G, 22G, 23G, 25G, 26G, 27G, 29G, 30G, 31G, 32G, 33G, 34G
ETW (Extra Thin Wall) : 18G, 19G, 21G, 22G, 23G, 29G, 30G, 31G, 32G, 33G, 34G
UTW (Ultra Thin Wall) : 19G, 21G, 29G, 30G, 31G, 32G

5. Intended Use:

This device is intended for use to inject fluids into or withdraw fluids from parts of the body below the surface of the skin.

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.

Requirement – Test (ISO 7864)	**Testing report no.**	**Result**
Visual check	-PQC-90527-01 (1) (Needle inner and outer surfaces) -PQC-200217-01 (Cover inner and outer surfaces)	Pass
Dimension	-PQC-90527-01 (1) (Outer diameter of needle tube, Length of the needle tube, needle hub and hub hole) -PQC-200217-01 (Cover)	Pass
Elasticity	-PQC-90527-01 (1) (Needle)	Pass
Flexural strength	-PQC-90527-01 (1) (Needle) - PQC-200217-01 (Cover strength)	Pass
Pullout	-PQC-90527-01 (1) (Needle) -PQC-200217-02 (Hub/needle bond strength)	Pass
Cleanliness	-PQC-200302-01	Pass
Limits for acidity or alkalinity	-PQC-200302-01	Pass
Limits for extractable metals	-PQC-200302-01	Pass
Needle hub (Conical fitting, Colour of hub)	-Refer to KTL test report for relevant test (20-008504-01-1 (Conical fitting)) -PQC-200302-01	Pass
Needle tube (Tolerances on length, Lubricant)	-PQC-200302-01	Pass
Needle point	-PQC-200302-01	Pass
Bond between hub and needle tube	-Refer to Poonglim Pharmatech Inc. test report for relevant test (PQC-200217-02 (Hub/needle bond strength))	Pass
Patency of lumen	-PQC-200302-01	Pass
Tolerances on length	-PQC-200508-07	Pass
Requirement – Test (ISO 9626)	**Testing report no.**	**Result**
Stiffness	-PQC-90821-01 (1)	Pass
Resistance to breakage		Pass
Resistance to corrosion		Pass
Cleanliness		Pass

Limits for acidity or alkalinity	-PQC-200302-02	Pass
Stiffness		Pass
Resistance to breakage		Pass
Resistance to corrosion		Pass
Requirement – Test (USP 41, <85>)	**Testing report no.**	**Result**
LAL test (Bacterial Endotoxin)	-T2018-14332	Pass
Requirement – Test (ISO 80369)	**Testing report no.**	**Result**
Luer connector performance	-20-008504-01-1	Pass
Dimension	-PQC-200225-01 (Luer)	Pass

2) Biocompatibility

Category: External Communicating Device

Contact: Blood path, indirect

Contact duration: A-limited (≤24h)

#	Test item	Test method / Test criteria	Test result
1	Cytotoxicity	ISO 10993-5 Tests for in vitro cytotoxicity	Pass
2	Skin Sensitization Test	ISO 10993-10 irritation and skin sensitization	Pass
3	Intracutaneous Reactivity Test	ISO 10993-10 Test for irritation and skin sensitization, maximization test for delayed hypersensitivity	Pass
4	Acute Systemic Toxicity Test	ISO 10993-11 Test for systemic toxicity – Acute Systemic Toxicity	Pass
5	Pyrogen Test	ISO 10993-11 Tests for systemic toxicity, Annex(F) Information on material-mediated pyrogens.	Pass
6	Hemolysis Test	ISO 10993-4 Selection of tests for interactions with blood	Pass
7	Particulate matter injections	USP <788> Particulate Matter in Injection	Pass

3) Sterility and LAL test

#	Test item	Test standard	Test result
1	LAL test	USP39 <85>, Bacterial Endotoxins Test (Unit : EU/Device)	Pass
2	E.O sterilization validation	According to ISO 11135:2014 E.O 30%, CO_2 70% Temperature : 55℃ Exposure time : 5 hours	Pass
3	Sterility test	According to ISO 11737-2	Pass
4	E.O Residual test	Under the conditions of ISO 10993-7:2008, Ethylene oxide sterilization residuals, the test articles should meet the test requirements.	Pass

The performance tests demonstrated that this device is performs in a substantially equivalent manner to the predicate device.

7. Comparison Table

Manufacturer	POONGLIM Pharmatech Inc.	POONGLIM Pharmatech Inc.	Remark
510(K) No.	K192222	K172483	
Intended use	This device is intended for use to inject fluids into or withdraw from parts of the body below the surface of the skin	This device is intended for use to inject fluids into or withdraw from parts of the body below the surface of the skin	Same
Hub of needle	Polypropylene (PP)	Polypropylene (PP)	Same
Protector	Polypropylene (PP)	Polypropylene (PP)	
Cannula	SUS304	SUS304	
Adhesive	Epoxy	Epoxy	
Length	4, 6, 8, 13, 16, 25, 30, 40mm	13, 16, 25, 40mm	See discussion below
Gauge	18, 19, 21, 22, 23, 25, 26, 27, 29, 30, 31, 32, 33, 34G	30G	See discussion below
Tip configuration	Bevel	Bevel	Per 7864:2016 Section 4.11
Cover dimension	Y type : 49 mm, 63 mm I type : 51 mm, 65 mm L type : 61 mm, 75 mm	Y type : 49 mm, 63 mm I type : 51 mm, 65 mm	Similar
Cover strength	Y type (63 mm) : 2.0 N I type (65 mm) : 3.5 N L type (65 mm) : 2.5 N	Y type (63 mm) : 2.0 N I type (65 mm) : 3.5 N	Similar
Hub/needle bond strength	18 G-40 mm : 137.7 N 19 G-40 mm : 177.8 N 21 G-25 mm : 82.0 N 22 G-25 mm : 114.0 N 23 G-25 mm : 144.3 N 25 G-13 mm : 91.1 N 26 G-13mm : 74.0 N 27 G-13 mm : 82.0 N 29 G-13 mm : 71.3 N 30 G-13 mm : 67.6 N 31 G-4 mm : 45.0 N 32 G-4 mm : 43.5 N 33 G-8 mm : 22.6 N 34 G-8 mm : 29.0 N	30 G-13 mm : 67.5 N	Similar Although we compared only 30 G, the rest of the gauges meet the requirements of the ISO 7864.

Length: The additional lengths meet the requirements of ISO 7864:2016, ISO 9626:2016, ISO 80369-7:2016 and ISO 6009:2016. The 4mm needle has a minimum specification of 3.5mm to successfully inject fluids or withdrawal fluids below the surface of the skin.

Gauge: The additional gauge sizes meet the requirements of ISO 7864:2016, ISO 9626:2016, ISO 80369-7:2016 and ISO 6009:2016.

8. Conclusion

The device has completed testing to show that the device meets its intended use and demonstrates substantial equivalence to the predicate device, K172483. Therefore, it is concluded that the subject device, EZ-Inject Single use Needle, is substantially equivalent to the legally marketed predicate device, K172483.