June 21, 2018

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

Re: K172483
Trade/Device Name: Kopac Sterile needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: June 20, 2018
Received: June 20, 2018

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. 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.

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,

Carolyn C. Dorgan -S

Digitally signed by Carolyn C. Dorgan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001800814, cn=Carolyn C. Dorgan -S
Date: 2018.06.21 16:21:51 -04'00'

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)*
K172483

Device Name
Kopac Sterile 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.

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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"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: POONGLIM Pharmatech Inc.
2) Address: 21, Jayumuyeok 1-gil, Gunsan-si, Jeollabukdo-do, Korea
3) Tel : 82-63-451-8141
4) Fax : 82-63-451-8145
5) Prepared date : July 11, 2017
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

2. Device Information

1) Trade name : Kopac Sterile Needle
2) Common name : Single-use needle, hypodermic needle
3) Classification name : Hypodermic Single Lumen Needle
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

K102584, IMC hypodermic 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.

Lengh of cannula by type

Model		Gauge	Inch (")	mm	Length of Cannula (A)	Cover dimension (mm)
Type Y and I	30-4	30G	1 1/2	40	40(+1.5/-2.5)	60
	30-3		1	25	25(+1.5/-2.5)	60
	30-2		5/8	16	16(+1/-2)	60
	30-1		1/2	13	13(+1/-2)	60

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)	Result
Inner and Outer Surface There must be bumps and flaws on the outer surface. The finished surface must be smooth, and the entire needle tuve must have undergone elecrolytic polishing or equivalent	Pass

polishing treatment.	
There must be no hazardous oxides, dusts and powders on the inner surface	Pass
The blade of the needle tuve must be sharply polished without visible bending and have uniform cross section and thickness.	Pass
When injecting glycerin into the needle tuve or needle hub, coloring of glycerin should not take place.	Pass
When a lubricant is applied on the needle tube, the lubricant must be non-toxic and satisfy ISO 7864. When observed by unaided eyes, no lubricant drops should be found on the inner and outer surfaces of the needle tube.	Pass
Dimensions Measured using digital vernier calipers and digital thickness gauge Outer diameter of the needle tube must be satisfied. Length of the needle tube must be satisfied.	Pass
The needle hub and hub hole When the test gauge indicated on the figure below is inserted into the hub hole at low pressure, the taper must fit with the taper gauge of the hub hole. Also, the nozzle of the needle hub must be within the gauge limit.	Pass
Elasticity Return to original position when bent to 12° using a protractor	Pass
Flexural strength No snapping when bent to 90° using a protractor	Pass
Pullout Measurement of maximum value using a tension and compression tester	Pass

Requirement – Test (ISO 9626)	**Result**
Stiffness When tested in accordance with the method given in ISO 9626 Annex B, apply a downward force given in table at a speed 1 mm/min. Measure the deflection of the tubing at the point of application of the force.	Pass
Resistance to breakage The cannula edg When tested in accordanc with Annex C, the tubing shall not show visible breakage when examined by normal or corrected vision. e shall be sharply ground to a regular cross-section and thickness, with no visible bending	Pass
Resistance to corrosion When tested in accordance with the method given in ISO 9626 Annex D, the tubing is partially immersed in sodium chloride solution(c(NaCl) = 0.5mol/L) at (23±2)℃, for 7h±5min. The immersed half of the tubing shall show no evidence of corrosion resulting from the test compared visully with the unimmersed portion.	Pass

2) Biocompatibility

#	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

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.	International Medsurg Connection (IMC)	Remark
510(K) No.		K102584	
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
Material			
Hub of needle	Polypropylene (PP)	Polypropylene (PP)	Same
Protector	Polypropylene (PP)	Polypropylene (PP)	
Cannula	SUS304	SUS 304	
Adhesive	Epoxy	Epoxy Resin	
Length	1/2”, 5/8”, 1” & $1\frac{1}{2}$”	1/2”, 5/8”, 3/4”, 7/8”, 1” ,$1\frac{1}{4}$” & $1\frac{1}{2}$”	Similar Including predicate device
Gauge	30G	16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G & 30G	Similar Including predicate device
Cover dimension	1/2” size: 60mm 1” size: 60mm 5/8” size : 60mm $1\frac{1}{2}$” size: 60mm	1/2” size: 40mm 5/8” size: 40mm 3/4” size: 40mm 7/8” size: 40mm 1” size: 40mm $1\frac{1}{4}$” size: 56mm $1\frac{1}{2}$” size: 56mm	Similar
Tip configuration	Bevel	Bevel	Same

8. Conclusion

The device has completed testing to show that the device meets its intended use and demonstrates substantial equivalence to the predicate device, K102584. Therefore, it is concluded that the subject device, Kopac Sterile Needle, is substantially equivalent to the legally marketed predicate device, K102584.