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

September 21, 2016

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

Re: K151090
Trade/Device Name: CPL Insulin Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: August 16, 2016
Received: August 23, 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151090

Device Name
CPL Insulin Pen Needle

Indications for Use *(Describe)*
This is a single use sterile insulin pen-injector needle to be used by diabetic patients for the purpose of injecting insulin.

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.

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510(k) Summary

[as required by 807.92(c)]

K151090

1. Applicant

1) Company : CPL Co.,Ltd.
2) Address : 36, Yongteurim-gil, Danwon-gu, Ansan-si, Gyeonggi-do, Korea
3) Tel : 82-31-483-7301
4) Fax : 82-31-483-7351
5) Contact person : Peter Chung, 412-687-3976
6) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
7) Date prepared : September 16, 2016

2. Device Information

1) Trade Name : CPL 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 (Company : Feel Tech)

4. Device description

CPL insulin pen needle consist of a sterile cap, needle cap, needle, hub and blister paper. The sterile cap and blister 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.

	Model	Needle length (mm) :	
Patient-side tip	CPLPN-29	8mm, 10mm, 12mm	
	CPLPN-30	5mm, 8mm, 10mm, 12 mm	
	CPLPN-31	4mm, 5mm, 6mm, 8mm	
	CPLPN-32	4mm, 5mm, 6mm, 8mm	
Cartridge-side tip	CPLPN-29	5mm,	
	CPLPN-30		
	CPLPN-31		
	CPLPN-32		
Needle taper		3.5mm	
Wall type (Thin-walled)	Needle gauge	Range of out diameters	Inside diameter of tubing
	CPLPN-29	29G(0.324mm~0.351mm)	29G (0.190)
	CPLPN-30	30G (0.298mm~0.320mm)	30G (0.165)
	CPLPN-31	31G (0.254mm~0.267mm)	31G (0.125)
	CPLPN-32	32G (0.229mm~0.241mm)	32G (0.105)

5. Intended Use :

This is a single use sterile insulin pen-injector needle to be used by diabetic patients for the purpose of injecting insulin.

6. Performance data:

In accordance with ISO 10993-1, CPL Insulin Pen Needle is classified as : Externally Communicating Device, Blood Path Indirect, Shor Term (<24 hours) Use, as the cannula is immediately withdrawn after injection into the body. This classification was chosen as "worst case scenario."

PER ISO 10993-1, the following tests were performed for this classification:

1. Cytotoxicity
2. Sensitization
3. Intracutaneous reactivity (Acute)
4. Systemic toxicity (Acute)
5. Pyrogenicity
6. Hemolysis

Bench tests relating to the performance of the "CPL Insulin Pen Needle" were conducted.
The principal device demonstrated equivalent performance to the predicate devices during bench testing. Bench testing consisted of:

Inner/outside and structure	Test standard ISO 11608-2 ISO 7864 ISO 9626
Dimension	
Draw test	
Elasticity test	
Flexual rigidity	
Inner and outside of needle	
Size designation	
Elasticity of the needle tube	
Pull	
Luricant	
Limits for acidity and alkalinity	
Stiffness	
Resistance to breakage	
Resistance to corrosion	
Determination of flow rate through the needle	
Bond between hub and needle tube	
Freedom from defects	
Penetration resistance	
Cap-hub fitting strength	
Dislocation of measuring point at patient end	
Needle dose accuracy test	
Needle hub torque removal	
Ease of assembly and disassembly test	
Compatibility with needle-based injection systems	

The performance tests demonstrated that CPL Insulin Pen Needle is performes in a substantially equivalent manner to the predicate device.

Compatible pens

Victoza Liraglutide injection	HumaLog KwikPen
Apidra SoloStar	HumaLog Mix 75/25 KwikPen
Lantus SoloStar	HumaLog Mix 50/50 KwikPen
OptiClik for Lantus and Apidra	Humalog Pen
SymlinPen 120 (pramlintide acetate) pen injector	Humalog Mix 75/25 Pen
SymlinPen 60 (pramlintide acetate) pen injector	Humalog Mix 50/50 Pen
Byetta exenatide injection 10mog	Humulin N Pen
Byetta exenatide injection 5mog	Humulin 70/30 Pen
Levemir FlexPen	HumaPen LUXURA HD
Novolog FlexPen	HumaPen MEMOIR
Novolog Mix 70/30 FlexPen	AutoPen
NovoPen Junior	Forteo teriparatide (rDNA origin) injection
NovoPen 3	

7. Predicate device comparison table

Manufacturer	CPL Co.,Ltd.				Feel Tech	Results
510(k) No.	K151090				K080904	N/A
Indication for use	This is a single use sterile insulin pen-injector needle to be used by diabetic patients for the purpose of injecting insulin.				These disposable sterile insulin pen needles are intended for subcutaneous injection of insulin in the treatment of diabetes.	Same intended use
Product name	Hypodermic single lumen needle				Hypodermic single lumen needle	Identical
Trade name	CPL Insulin Pen Needle				Feel Fine Insulin Pen Needle	N/A
Model/type	CPLPN-29, CPLPN-30, CPLPN-31, CPLPN-32				Feel Fine Insulin Pen Needle-29 Feel Fine Insulin Pen Needle-30 Feel Fine Insulin Pen Needle-31	
Appearance						Similar design
Product configuration	Hub Needle cap Sterile cap Needle Sterile paper				Hub Needle cap Sterile cap Needle Sterile paper	Similar device componenets
Material	Sterile cap : Polypropylene Needle cap : Polyethylene Needle : Stainless steel 304 Hub : Polypropylene				Sterile cap : Polypropylene Needle cap : Polyethylene Needle : Stainless steel 304 Hub : Polypropylene	Similar material
Length of parts (mm)						
Total length of assembly	29.8				28.8	Similar dimensions
Side length of assembly(max)	15.2				15.5	
Inner diameter of sterile cap	11.2				12.95	
Gauge	29G	30G	31G	32G	29, 30, 31G	Similar
Length of needle	8 ㎜ 10 ㎜ 12 ㎜	5 ㎜ 8 ㎜ 10 ㎜ 12 ㎜	4 ㎜ 5 ㎜ 6 ㎜ 8 ㎜	4 ㎜ 5 ㎜ 6 ㎜ 8 ㎜	5 ㎜ 8 ㎜ 12.7 ㎜	Similar needle length
Sterilization	EO Gas sterilization				EO Gas sterilization	Same
Packagine	Sterile cap(PP)+sterile paper				Sterile cap(PP)+sterile paper	Similar
Performance test	Accordance with ISO 11608-2				N/A	Suitable
Biocompatibility	Accordance with ISO 10993 series				N/A	Suitable

The device is investigated for function and effectiveness to compare the operation of function between CPL Co.,Ltd. and Feeltech (K080904). Comparison results demonstrate that the specifications and performance of the device are same as functional and effective as the legally marketed predicate device. Therefore, it is concluded that is Insulin pen needle of CPL Co.,Ltd. substantially equivalent to the legally marketed predicate device.

Intended use statement is similar with that of the predicate device. They are both single use only, used for insulin injection and for diabetes treatment. The difference in wording of these intended use does not change the intended use or raise questions of safety and effectiveness per 807.92(a)(5).
The bench tests of Needles with 32G demonstrated conformances to ISO 11608-2 and ISO 7864. Therefore the differences do not raise new concerns to establish substantial equivalence to the predicate.

9. Conclusion:

The subject device has been tested according to ISO 11608-2:2012 (Needle-based injection systems for medical use-Requirements and test methods-Part 2:Needles) as well as ISO 9626 (stainless steel tubing for manufacture of medical devices) and test results demonstrated it is substantial equivalent to as the cited predicate device.