January 17, 2021

Nanum Company Co., Ltd
% Peter Chung
President
Plus Global
300 Atwood St.
Pittsburgh, Pennsylvania 15213

Re: K201930
Trade/Device Name: Nanum Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: June 24, 2020
Received: July 10, 2020

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. 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,

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K201930

Device Name
Nanum Syringe

Indications for Use *(Describe)*
Nanum Syringe is the plastic syringe for Single use, with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

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.

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510(k) Summary

1. Applicant

1) Company : NANUM COMPANY Co., Ltd
2) Address : 4th floor, 40, Siji-ro, Suseong-gu, Daegu, Korea
3) Tel : 82-53-795-7076
4) Fax : 82-53-795-7078
5) Prepared date : June 24, 2020
6) Contact person : Peter Chung, 412-512-8802
7) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
8) Submission date : Nov. 20, 2020

2. Device Information

1) Trade name : Nanum Syringe
1) Common name : Piston Syringe
2) Regulation name : Syringe, Piston
3) Product code : FMF
4) Regulation number : 880.5860
5) Class of device : Class II
6) Panel : General Hospital

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

K190002, Shanghai Kohope Medical Devices Co., Ltd. / Sterile Hypodermic Syringe for Single use, with/without needle

4. Device description

A sterile device consisting of a calibrated barrel (cylinder) with plunger intended to be used for injection/withdrawal of fluids/gas (e.g., medication) to/from a medical device or the body (i.e., capable of both); a needle is not included. It is intended for various medical applications and is not dedicated to medication administration. At the distal end of the barrel is a male connector (typically Luer-lock/slip type) for the attachment to a hypodermic needle or an administration set. It is typically made of plastic and silicone materials and may have anti-stick plunger allowing smooth plunger movement, either manually or by a syringe pump. This is a single-use device.

5. Intended Use

Nanum Syringe is the plastic syringe for Single use, with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.

6. Performance data:

1) Bench test were performed. Bench testing included biocompatibility and mechanical testing. 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.

Test item	Reqirements	Results
Appearance and Structure	MFDA Notification No. 2018-72, The standards for the medical device	Pass – MTK-2019-000829
Nozzle	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use	
Scale	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use	
Piston/Plunger Assembly	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use	

Tightness	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use	
Extraction test : pH	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use	
Extraction test : Heavy metal	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use	
Extraction test : Potassium permanganate-reducible substances	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use	
Extraction test : Residue on evaporation	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use	
Quantity of silicone oil	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use	
Shelf life test	ASTM1980-07: 2011 Standard guide for Accelerated Aging of Sterile Barrier System for Medical Device ISO11607-1:2006 Packaging for terminally sterilized medical devices	NC-SLR-1902
	Performance test of Real time and accelerated aged devices	NC-060-F0729 NC-060-F0421

2) Biocompatibility

#	Test item	Test method / Test criteria	Test result
1	Cytotoxicity	ISO 10993-5(2009) Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Pass
2	Acute systemic toxicity test	ISO 10993-11(2009) Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	Pass
3	Pyrogen test	ISO 10993-11 Test for systemic toxicity, pyrogen test	Pass
4	Sensitization test	ISO 10993-10 (2010)	Pass
5	Hemolytic test	ISO 10993-4:2017, ASTM F756-17	Pass
6	Intracutaneous reactivity test	ISO 10993-10 (2010)	Pass
7	LAL Test	ISO 10993-11 Test for systemic toxicity, pyrogen test	Pass MSK-2020-002259

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

7. Predicate device comparison table

Manufacturer	NANUM COMPANY Co., Ltd	Shanghai Kohope Medical Devices Co., Ltd.	Remark
510(k) No.		K190002	N/A
Indication for use	Nanum Syringe is the plastic syringe for Single use, with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	The sterile Hypodermic Syringe for Single use, with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body.	Similar
Classification name	Syringe, Piston	Syringe, Piston	Same

Manufacturer	NANUM COMPANY Co., Ltd	Shanghai Kohope Medical Devices Co., Ltd.	Remark
Trade name	Nanum Syringe	Sterile Hypodermic Syringe for Single use, with/without needle, Sterile Insulin Syringe for Single use, with needle, Sterile Hypodermic needle for Single use	N/A
Model/type	NS-10, NS-20, NS-50	N/A	N/A
Components	Cylinder, Plunger, Gasket, Clip	Barrel, Plunger, Piston	Similar
Nozzle type	Lock type, Lock clip type	Lock and Slip type	Similar
Materials Barrel Plunger Piston	 PP PP Rubber	 PP PP Rubber	Same
Capacity	10mL, 20mL, 50mL	1mL, 2mL, 3mL, 5mL, 10mL, 20mL, 30mL, 35mL, 50mL, 60mL	Similar
Principle of operation	Manual	Manual	Same
Performances	Complies with ISO 7886-1 : 2017 Sterile hypodermic syringes for single use – Part 1 : Syringes for manual use	Complies with ISO 7886-1 : 2017 Sterile hypodermic syringes for single use – Part 1 : Syringes for manual use	Same
Biocompatibility	Cytotoxicity Acute systemic toxicity Pyrogenicity Sensitization Hemolysis Intracutaneous test Endotoxin (LAL) test	Cytotoxicity Acute systemic toxicity Pyrogenicity Sensitization Irritation Subacute toxicity	Similar
Principle of Operation	The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.	The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.	Same

8. Conclusion

The device is investigated for function to compare the operation of function between Nanum Syringe and predicate devices.

Comparison results demonstrate that the specifications and performance of the device are substantially equivalent to the legally marketed predicate device.

Therefore, it is concluded that Nanum Syringe are substantially equivalent to the legally marketed predicate device.