December 14, 2018

Jiangsu Caina Medical Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 Cn

Re: K181374
Trade/Device Name: NRFit Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QEH
Dated: October 31, 2018
Received: November 13, 2018

Dear Diana Hong:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Sarah B. Mollo -S

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)*
K181374

Device Name
NRFit Syringe

Indications for Use *(Describe)*
The device is indicated for local administration, and regional administration, specifically, wound infiltrations, peripheral nerve block, and epidural block. The device is not indicated for subarachnoid/spinal blocks.

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.

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

K181374

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K181374

1. Date of Preparation: 12/12/2018

2. Sponsor Identification

Jiangsu Caina Medical Co., Ltd.
No.23, Huanxi Road, Zhutang Town, Jiangyin, Jiangsu, 214425, China

Establishment Registration Number: 3005670221

Contact Person: Jun Lu
Position: General Manager
Tel: +86-510-86205183
Fax: +86-510-86215183
Email: junlu@cainamedical.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 001-3609253199
Email: info@mid-link.net

4. Device

Trade Name: NRFit Syinge
Common Name: Syringe, piston
Model(s): 1ml, 3ml, 5ml, 6ml, 10ml, 20ml, 30ml, 35ml, 50ml and 60 ml

Regulatory Information

Classification Name: Piston Syringe
Classification: II
Product Code: QEH
Regulation Number: 21 CFR 880.5860
Review Panel: General Hospital

5. Predicate Device

510(k) Number: K170218
Product Name: Vesco Medical NRFit™ Syringes

6. Device Description

The proposed device is a disposable neuraxial syringe consist of three components: piston, plunger and barrel; and provided in a variety of volumes: 1ml, 3ml, 5ml, 6ml, 10ml, 20ml, 30ml, 35ml, 50ml and 60 ml. The barrel of the syringe is printed with graduated markings indicating the volume of liquid inside the barrel.

The proposed device is used to inject anesthesia medicine with the cooperation of the spinal anesthesia needles and epidural anesthesia needles which has an NRFit connectors in compliance with ISO 80369-6. The NRFit tip could help to reduce the residual risk of misconnections.

The proposed device is provided in two statuses: sterile and non-sterile. The non-sterile NRFit syringe is intended to be sterilized prior to use to repackagers/medical device manufacturers, and the sterile NRFit syringe is supplied to the end user. The sterilized product is sterilized by Ethylene Oxide Gas to achieve a SAL of 10^{-6} and supplied sterility maintenance package which could maintain the sterility of the device during the shelf life of five years.

7. Indications for Use:
The device is indicated for local administration and regional administration, specifically, wound infiltrations, peripheral nerve block, and epidural block. The device is not indicated for subarachnoid/spinal blocks.

8. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-7:2008 Biological evaluation of medical devices- Part 7: Ethylene Oxide Sterilization Residuals
- ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Test for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Test for irritation and delayed-type hypersensitivity
- ASTM F1929-15 Standard test method for detecting seal leaks in porous medical packaging by dye penetration.
- ASTM F88/F88M-15 standard method for seal strength of flexible barrier materials
- USP 39-NF34 <85> Bacterial Endotoxins Test
- ISO 7886-1:1993 Sterile hypodermic syringe for single use- Part 1: Syringes for manual use
- ISO 80369-6:2016 Small bore connectors for liquids and gases in healthcare applications –Part 6: Connectors for neuraxial applications
- ISO 80369-20:2015 Small bore connectors for liquids and gases in healthcare applications- Part 20: Common test methods
- USP <788> Particulate Matter in Injections (Method 1)

Connector testing performed on the proposed device included the items listed below, in accordance with ISO 80369-6:2016, using the test methods provided in ISO 80369-20. The testing demonstrates the proposed devices conform to the requirements of ISO 80369-6:2016.

Individual test Defined in ISO 80369-6	Requirement Defined in ISO 80369-6	Test Method Defined in ISO 80369-20
Fluid Leakage	Clause 6.1	Annex C
Stress Cracking	Clause 6.3	Annex E
Resistance to separation from axial load	Clause 6.4	Annex F
Resistance to separation from unscrewing	Clause 6.5	Annex G
Resistance to overriding	Clause 6.6	Annex H

Syringe testing performed on the proposed device included the items listed below, in accordance with ISO 7886-1:1993, Sterile hypodermic syringe for syringe use-Part 1: Syringe for manual use, using the test methods provided in ISO 7886-1:1993. The testing demonstrates the proposed devices conform to the requirements of ISO 7886-1:1993.

Individual test Defined in ISO 7886-1:1993	Requirement Defined in ISO 7886-1:1993
Cleanliness	Clause 5
Limits for acidity or alkalinity	Clause 6

Limits for extractable metals	Clause 7
Lubricant	Clause 8
Tolerance on graduated capacity	Clause 9
Graduated scale	Clause 10
Barrel	Clause 11
Piston/plunger assembly	Clause 12
Dead space	Clause 14.1
Freedom from air and liquid leakage past piston	Clause 14.2

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Substantially Equivalent (SE) Comparison

Table 1 Substantial Equivalence

ITEM	Proposed Device	Predicate Device K170218	Remark
Product name	NRFit Syringe	Vesco Medical NRFit™ Tip Syringes	/
Product code	FMF	FMF	SE
Regulation No.	21 CFR 880.5860	21 CFR 880.5860	SE
Class	II	II	SE
Indications for Use	The device is indicated for local administration, and regional administration, specifically, wound infiltrations, peripheral nerve block, and epidural block. The device is not indicated for subarachnoid/spinal blocks.	The Vesco Medical NRFit™ Tip Syringes are intended to inject fluids into or withdraw fluids from the body.	Analysis is provided below
Configuration	Piston Plunger Barrel	Piston Plunger Barrel	SE
Sterility condition	EO Sterilized/ Non-sterilized	EO Sterilized	Analysis is provided below
Environment of use	Hospital	Hospital	SE

Intended users	Medical professionals and trained care givers	Medical professionals and trained care givers	SE
Single use	Yes	Yes	SE
Type of placement	Used with catheter or needle with Neuraxial compliant connector	Used with catheter or needle with Neuraxial compliant connector	SE
NRFit Connector	Yes; compliant with ISO 80369-6	Yes; compliant with ISO 80369-6	SE
Operation mode	For Manual Use Only, For Single Use only	For Manual Use Only, For Single Use only	SE
Label/labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	SE

Comparison summary

The differences between the proposed device and predicate device are the volume and sterilization status. The proposed device has a larger range of volumes than the predicate device. Both the proposed device and the predicate device comply with the relevant international standards stated in Section 8, which includes verification of attributes that could be impacted by syringe volume/barrel size. Therefore, the difference in syringe volume will not raise different questions of safety and effectiveness. The proposed device is provided in two presentations: sterile and non-sterile. The non-sterile NRFit syringe is intended to be sterilized prior to use to repackagers/medical device manufacturers and the sterile NRFit syringe is supplied to the end user. The sterilized product is sterilized by Ethylene Oxide Gas to achieve a SAL of 10^{-6}, which is the same as the predicate device. The non-sterile product is clearly labeled and validated cycle conditions for EO sterilization are provided to the repackagers/medical device manufacturers. Therefore, the differences will not affect the substantial equivalence between the proposed device and predicate device.

11. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device.