DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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February 24, 2017

Vesco Medical, LLC
% Mark Job
Official Correspondent
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K170218
Trade/Device Name: Vesco Medical NRFit Tip Syringes
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: January 23, 2017
Received: January 25, 2017

Dear Mark Job:

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,

Michael J. Ryan -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Vesco Medical NRFit™ Tip Syringes

Indications for Use *(Describe)*
The Vesco Medical NRFit™ Tip Syringes are intended to inject fluids into or withdraw fluids from the 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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TAB 6
510(k) Summary

I. Submitter

Official Contact

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Date of Preparation November 04, 2016

II. Device

Name of Device: Vesco Medical NRFit™ Tip Syringes

Common/Usual Name: Syringe, Piston

Device Classification: Class II

Classification Name/ Product Code: General Hospital and Personal Use Devices (21 CFR 880.5860) / FMF

III. Legally Marketed Predicate Devices

- Jiangyin Caina Technology Co., Ltd (Caina) *Syringes With or Without Needles (Luer Slip/Lock)* were cleared under notification K113091.
- Shanghai Kindly Enterprises *Sterile Hypodermic Syringe for Single Use, With or Without Needle (Luer Slip/Lock)* were cleared under notification K112057.

IV. Device Description

The Vesco Medical NRFit Tip Syringes are sterile, single use devices consisting of rigid polypropylene barrels and plungers with a synthetic rubber gasket. The tips of the syringe barrels are NRFit ISO 80369-6 compliant. The NRFit tip allows for connections of neuraxial specific applications while reducing the likelihood of misconnections to non-neuraxial devices. The syringe barrel is printed with graduated markings indicating, in milliliters, the volume of liquid inside the syringe barrel. The proposed models are listed in Table 6.1.

Table 6.1: Proposed models of Vesco Medical NRFit Tip Syringes

Vesco Medical NRFit Tip Syringes	
Model #	**Volume**
VND-603EO	3 mL
VND-610EO	10 mL
VND-620EO	20 mL

V. Intended Use

The Vesco Medical NRFit™ Tip Syringes are intended to inject fluids into or withdraw fluids from the body.

VI. Comparison of Technological Characteristics with the Predicate Device

The proposed Vesco Medical NRFit Tip Syringes and the predicate devices are all intended to inject fluids into or withdraw fluids from the body. These products have similar intended uses, technological characteristics, manufacturing methods, and operating principles. There are no significant differences that would affect the performance of the Vesco Medical NRFit Tip Syringes as compared to the predicate devices. Table 6.2 lists the comparisons of the proposed device to the predicate devices.

Table 6.2: Comparison of Vesco Medical NRFit Tip Syringes to predicate devices regarding substantial equivalence (SE), similarities, and differences.

Design Features / Function	**Syringes With or Without Needles K113091 (Primary Predicate)**	**Sterile Hypodermic Syringe for Single Use, With or Without Needle K112057 (Secondary Predicate)**	**Vesco Medical NRFit™ Tip Syringes (Proposed)**	**Substantial Equivalence**
Indications for Use	Syringes with or without needle are intended to inject fluids into or withdraw fluids from the 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.	The Vesco Medical NRFit™ Tip Syringes are intended to inject fluids into or withdraw fluids from the body.	Substantially equivalent.
Intended Use	Syringes with or without needle are intended to inject fluids into or withdraw fluids from the 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.	The Vesco Medical NRFit™ Tip Syringes are intended to inject fluids into or withdraw fluids from the body.	Substantially equivalent.
Environment of Use	Unspecified, hospital use implied	Unspecified, hospital use implied	Hospital	Similar to both.

Design Features / Function	**Syringes With or Without Needles K113091 (Primary Predicate)**	**Sterile Hypodermic Syringe for Single Use, With or Without Needle K112057 (Secondary Predicate)**	**Vesco Medical NRFit™ Tip Syringes (Proposed)**	**Substantial Equivalence**
Intended Users	Trained Clinicians (implied)	Trained Clinicians (implied)	Medical Professionals and trained care givers	Similar to both. There are no differences in intended users that would impact equivalence.
Patient Population	RX only	RX only	RX only, patients over 1 year	Similar to both. There are no differences in patient population that would impact equivalence.
Single Use	Yes	Yes	Yes	Substantially equivalent.
Sterility Condition	Sterile (EtO) and non-pyrogenic	Sterile (method unspecified)	Sterile (EtO) and non-pyrogenic	Substantially equivalent.
Type of placement	Used with catheter or needle	Used with catheter or needle	Used with catheter or needle with Neuraxial compliant connector	The NRFit connector does not change the intended use or function of the proposed device. From the Risk Analysis and DFMEA, it was found that the NRFit connector helps reduce the residual risk of misconnections.
NRFit Connector	No; Luer Slip/Lock connector.	No; Luer Slip/Lock connector.	Yes; compliant with ISO 80369-6.	The NRFit connector does not change the intended use or function of the proposed device. From the Risk Analysis and DFMEA, it was found that the NRFit connector helps reduce the residual risk of misconnections.
Syringe Barrel and Plunger Material	Polypropylene	Polypropylene	Polypropylene	Substantially equivalent.
Syringe Piston Material	Synthetic Rubber	Synthetic Rubber	Synthetic Rubber	Substantially equivalent.
Syringe Piston Lube Coating	Polydimethylsiloxane, Silanol Terminated	Medical Grade Silicone	Polydimethylsiloxane, Silanol Terminated	Substantially equivalent.

Design Features / Function	**Syringes With or Without Needles K113091 (Primary Predicate)**	**Sterile Hypodermic Syringe for Single Use, With or Without Needle K112057 (Secondary Predicate)**	**Vesco Medical NRFit™ Tip Syringes (Proposed)**	**Substantial Equivalence**
Markings on Syringe for Measuring Liquid Volume	TAMPAPUR TPU	Black Medical Grade	TAMPAPUR TPU	Substantially equivalent.
Volumes	Various volume sizes based upon customer request	1 mL, 2 mL, 3 mL, 5 mL, 10 mL, 20 mL, 30 mL, 35 mL, 50 mL	3 mL, 10 mL, 20 mL	Similar to both. 3, 10 and 20 mL are a subset of sizes cleared under both.
Biocompatibility	Biocompatibility testing has demonstrated that this device meets guidelines presented in ISO 10993-1:2009, with the FDA modified matrix presented in General Program Memorandum # G95-1	Biocompatibility testing has demonstrated that this device meets guidelines presented in ISO 10993-1:2009, with the FDA modified matrix presented in General Program Memorandum # G95-1	Same materials, manufacturer, manufacturing materials as primary predicate	Substantially equivalent.
Piston/Plunger Assembly Testing	Tested and met standards of ISO 7886-1:1993 Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use	Tested and met standards of ISO 7886-1:1993 Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use	Tested and met standards of ISO 7886-1:1997 Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use	Substantially equivalent.
Dead Space Testing	Tested and met standards of ISO 7886-1:1993 Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use	Tested and met standards of ISO 7886-1:1993 Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use	Tested and met standards of ISO 7886-1:1997 Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use	Substantially equivalent.
Air Leakage Past Syringe Piston During Aspiration Testing	Tested and met standards of ISO 7886-1:1993 Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use	Tested and met standards of ISO 7886-1:1993 Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use	Tested and met standards of ISO 7886-1:1997 Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use	Substantially equivalent.
Liquid Leakage Past Syringe Piston Under Compression Testing	Tested and met standards of ISO 7886-1:1993 Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use	Tested and met standards of ISO 7886-1:1993 Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use	Tested and met standards of ISO 7886-1:1997 Sterile Hypodermic Syringes for Single Use – Part 1: Syringes for Manual Use	Substantially equivalent.

Design Features / Function	**Syringes With or Without Needles K113091 (Primary Predicate)**	**Sterile Hypodermic Syringe for Single Use, With or Without Needle K112057 (Secondary Predicate)**	**Vesco Medical NRFit™ Tip Syringes (Proposed)**	**Substantial Equivalence**
Fluid Leakage: Connector	Not Applicable; no NRFit Connector	Not Applicable; no NRFit Connector	Tested per ISO 80369-20 and met the standards of ISO 80369-6 for positive pressure fluid leakage.	The NRFit connector does not change the intended use or function of the proposed device. From the Risk Analysis and DFMEA, it was found that the NRFit connector helps reduce the residual risk of misconnections.
Air Leakage: Connector	Not Applicable; no NRFit Connector	Not Applicable; no NRFit Connector	Tested per ISO 80369-20 and met the standards of ISO 80369-6 for sub atmospheric pressure air leakage.	The NRFit connector does not change the intended use or function of the proposed device. From the Risk Analysis and DFMEA, it was found that the NRFit connector helps reduce the residual risk of misconnections.
Stress Cracking: Connector	Not Applicable; no NRFit Connector	Not Applicable; no NRFit Connector	Tested per ISO 80369-20 and met the standards of ISO 80369-6 for stress cracking.	The NRFit connector does not change the intended use or function of the proposed device. From the Risk Analysis and DFMEA, it was found that the NRFit connector helps reduce the residual risk of misconnections.

Design Features / Function	**Syringes With or Without Needles K113091 (Primary Predicate)**	**Sterile Hypodermic Syringe for Single Use, With or Without Needle K112057 (Secondary Predicate)**	**Vesco Medical NRFit™ Tip Syringes (Proposed)**	**Substantial Equivalence**
Resistance to separation from axial load: connector	Not Applicable; no NRFit Connector	Not Applicable; no NRFit Connector	Tested per ISO 80369-20 and met the standards of ISO 80369-6 Resistance to separation from axial load.	The NRFit connector does not change the intended use or function of the proposed device. From the Risk Analysis and DFMEA, it was found that the NRFit connector helps reduce the residual risk of misconnections.
Resistance to separation from unscrewing: connector	Not Applicable; no NRFit Connector	Not Applicable; no NRFit Connector	Tested per ISO 80369-20 and met the standards of ISO 80369-6 for Resistance to separation from unscrewing.	The NRFit connector does not change the intended use or function of the proposed device. From the Risk Analysis and DFMEA, it was found that the NRFit connector helps reduce the residual risk of misconnections.
Resistance to overriding: connector	Not Applicable; no NRFit Connector	Not Applicable; no NRFit Connector	Tested per ISO 80369-20 and met the standards of ISO 80369-6 for Resistance to overriding.	The NRFit connector does not change the intended use or function of the proposed device. From the Risk Analysis and DFMEA, it was found that the NRFit connector helps reduce the residual risk of misconnections.

Design Features / Function	Syringes With or Without Needles K113091 (Primary Predicate)	Sterile Hypodermic Syringe for Single Use, With or Without Needle K112057 (Secondary Predicate)	Vesco Medical NRFit™ Tip Syringes (Proposed)	Substantial Equivalence
NRFit Dimensional Verification	Not Applicable; no NRFit Connector	Not Applicable; no NRFit Connector	Evaluated per ISO 80369-20 and met the standards of ISO 80369-6 for NRFit dimensional verification.	The NRFit connector does not change the intended use or function of the proposed device. From the Risk Analysis and DFMEA, it was found that the NRFit connector helps reduce the residual risk of misconnections

VII. Performance Data:

Non-Clinical Tests

Verification and validation Testing was performed with the Vesco Medical NRFit Tip Syringes. It was found that Vesco Medical NRFit Tip Syringes are in compliance with design and performance requirements according to ISO 80369-6:2016 “Small-bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications,” ISO 80369-20:2016 “Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common Test Methods, “and BS EN ISO 7886-1:1997 “Sterile Hypodermic Syringes For Single Use – Part 1: Syringes For Manual Use.” A risk analysis and a Design FMEA were conducted on the Vesco Medical NRFit™ Tip Syringes; both yielded acceptable results.

The following testing was conducted on the Vesco Medical NRFit Tip Syringes:

1. Basic Syringe Functions per BS EN ISO 7886-1:1997 performed by Jiangyin Caina Technology Co., Ltd and Vesco Medical
2. Determination of Dead Space per BS EN ISO 7886-1:1997 performed by Jiangyin Caina Technology Co., Ltd and Vesco Medical
3. Liquid Leakage at Syringe Piston Under Compression per BS EN ISO 7886-1:1997 performed by Jiangyin Caina Technology Co., Ltd and Vesco Medical
4. Air Leakage Past Syringe Piston During Aspiration and for Separation of Piston and Plunger per BS EN ISO 7886-1:1997 performed by Jiangyin Caina Technology Co., Ltd and Vesco Medical
5. Fluid Leakage per ISO 80369-20:2015, performed by Jiangyin Caina Technology Co., Ltd
6. Stress Cracking per ISO 80369-20:2015, performed by Jiangyin Caina Technology Co., Ltd
7. Resistance to separation from axial load per ISO 80369-20:2015, performed by Jiangyin Caina Technology Co., Ltd
8. Resistance to separation from unscrewing per ISO 80369-20:2015, performed by Jiangyin Caina Technology Co., Ltd
9. Resistance to overriding per ISO 80369-20:2015, performed by Jiangyin Caina Technology Co., Ltd Disconnection by unscrewing per ISO 80369-20:2015, performed by Jiangyin Caina Technology Co., Ltd
10. NRFit dimensional verification per ISO 80369-6:2016, performed by Jiangyin Caina Technology Co., Ltd

Clinical Tests
Clinical tests were not required to demonstrate performance of Vesco Medical NRFitTM Tip Syringes. Product functionality has been adequately assessed by non-clinical tests.

Animal Tests
Animal tests were not required to demonstrate the performance of Vesco Medical NRFit Tip Syringes. Product functionality has been adequately assessed by non-animal tests.

VIII. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the Vesco Medical NRFit Tip Syringes are as safe, as effective, and perform as well as or better than the legally marketed devices identified in part III, “Legally Marketed Predicate Devices” of this section.

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