January 17, 2018

Novo Nordisk Inc.
Devraj Chakravarty
Senior Manager, Regulatory Affairs
P.O. Box 846
Plainsboro, New Jersey 08536

Re: K173479
Trade/Device Name: NovoFine® 32G Tip (0.23/0.25) x 6 mm ETW (extra thin wall)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: December 12, 2017
Received: December 13, 2017

Dear Devraj Chakravarty:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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)*

Device Name
NovoFine® 32 G Tip (0.23/0.25) X 6 mm ETW (extra thin wall)

Indications for Use *(Describe)*
Indications for Use: NovoFine® 32 G Tip (0.23/0.25) X 6 mm ETW needles are intended for use with pen injector devices for the subcutaneous injection of insulin, liraglutide, semaglutide and somatropin.

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."

K173479

510(k) Summary

21 CFR 807.87(h)

As required by 21 CFR 807.92(a)

(1) Date Prepared: November 7, 2017

This summary of 510(k) information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The NovoFine® 32 G Tip (0.23/0.25) x 6 mm ETW (extra thin wall) needle meets all applicable product standards for hypodermic single lumen needle products.

Submitter's Name and Address:

Novo Nordisk Inc.
800 Scudders Mill Road
Plainsboro, New Jersey 08536

Contact Person:
Devraj Chakravarty
Senior Manager, Regulatory Affairs
Tel: 609-786-5564
Fax: 609-681-5346

(2) Name of Device:

Proprietary Name:	NovoFine® 32 G Tip (0.23/0.25) x 6 mm ETW (extra thin wall)
Common or usual name:	Sterile disposable hypodermic needle
Classification Name:	Hypodermic single lumen needle (21 CFR 880.5570)
Class:	Class II
Product Code:	FMI

(3) Substantial Equivalence:

NovoFine® 32 G Tip 6 mm ETW needles are disposable needles which are substantially equivalent to the NovoFine® 32 G Tip 6 mm ETW cleared under K062500 and K090111.

No physical change has been made from K062500 cleared on November 21, 2006 and K090111 cleared on February 1, 2010. The only change was to include an additional drug name in the indication for use statement.

Table 1 Comparison to a Legally Marketed Device

Parameters	**NovoFine® 32G Tip x 6 mm ETW**	**NovoFine® 32G Tip x 6 mm ETW**
Marketing Status	Subject of this Premarket Notification	Cleared under [510(k) K062500 and K090111]
Intended use	Intended for use with pen injector devices for the subcutaneous injection of insulin, liraglutide, semaglutide and somatropin	Intended for use with pen injector devices for the subcutaneous injection of insulin, liraglutide, and somatropin
Product type	Hypodermic single lumen	Hypodermic single lumen
Durability	5 years from production date	5 years from production date
Biocompatibility	EN ISO 10993-1	EN ISO 10993-1
Reuse	Reuse	Reuse
Labeling	See Section 13: Proposed Labeling	See Section 13: Proposed Labeling-predicate labeling
Specifications		
Outer diameter, tip	0.22-0.25 mm	0.22-0.25 mm
Outer diameter, cylindrical part	0.22-0.27 mm	0.22-0.27 mm
Inner diameter	0.145-0.16 mm	0.145-0.16 mm
Wall thickness, tip	0.03-0.053 mm	0.03-0.053 mm
Wall thickness, cylindrical part	0.045-0.063 mm	0.045-0.063 mm

Parameters	NovoFine® 32G Tip x 6 mm ETW	NovoFine® 32G Tip x 6 mm ETW
Total length	15.82-16.88 mm	15.82-16.88 mm
Length from hub	6 mm	6 mm
Gauge	32	32
Tip configuration	1st and 2nd grinding and glass blasting	1st and 2nd grinding and glass blasting
Sealing paper strength	P_{min} = 70 mBar	P_{min} = 70 mBar
Demounting force, outer cap from hub	Pull force range 1 – 15 N	Pull force range 1 – 15 N
Demounting force,inner cap from hub	Pull force range 0.5 – 7 N	Pull force range 0.5 – 7 N
Hub/≤needle ≥ bond strength	F_{min} = 22 N	F_{min} = 22 N
Materials		
Hub	Polypropylene (PP) white master batch Color: White	Polypropylene (PP) white master batch Color: White

Parameters	NovoFine® 32G Tip x 6 mm ETW	NovoFine® 32G Tip x 6 mm ETW
Cannula	Stainless steel AISI / SUS 304 DIN-kurzname: X 5 CrNi 18 9	Stainless steel AISI / SUS 304 DIN-kurzname: X 5 CrNi 18 9
Glue	Single component epoxy adhesive Color: Light yellow	Single component epoxy adhesive Color: Light yellow
Inner needle cap	Polyethylene (PE) Color: White	Polyethylene (PE) Color: White
Outer needle cap	Polypropylene (PP) Color: Transparent white	Polypropylene (PP) Color: Transparent white
Sealing paper	Bactite 60K 43 g/m^2 coated with PS-118 laquer 6 g/m^2 for ethylene oxide sterilization Color: Light blue (RAL 5012)	Bactite 60K 43 g/m^2 coated with PS-118 laquer 6 g/m^2 for ethylene oxide sterilization Color: Light blue (RAL 5012)
Lubricating oil for patient needle end	MDX4-4159 fluid 50 % Medical Grade Dispersion (partly hardened silicone)	MDX4-4159 fluid 50 % Medical Grade Dispersion (partly hardened silicone)
Lubricating oil for back needle end	360 Medical Fluid Silicone Oil 12500 cSt	360 Medical Fluid Silicone Oil 12500 cSt

(4) Device Description:

NovoFine® 32 G Tip (0.23/0.25) 6 mm ETW needle is designed for single use. Prior to giving an injection, the protective tab is removed from the outer needle cap of the single-use

disposable needle. With the disposable needle remaining in the outer needle cap, it is then carefully screwed onto the injection delivery device until tight and then the needle outer and inner caps are removed. Use the needles as described in the instructions for use that comes with the pen-injector device and as instructed by the healthcare professional.

After the injection, the needle is removed from the skin. The needle is detached from the injection device and disposed of in accordance with national/local regulations. For each subsequent injection, a new disposable needle must be used.

The instructions for use are described in the user manuals for Novo Nordisk delivery devices for injection and are the same for all NovoFine® needles.

(5) Intended Use:

NovoFine® 32 G Tip (0.23/0.25) X 6 mm ETW needles are intended for use with pen injector devices for the subcutaneous injection of insulin, liraglutide, semaglutide and somatropin.

The intended use has been revised to include semaglutide. Performance data was provided to verify compatibility with semaglutide pen injector.

(6) Reprocessing, sterilization, shelf-life:

The sterilization process is identical to the predicate K062500. A summary of the sterilization information is provided below:

Table 1 Sterilization information for NovoFine® 32G (0.23x0.25) x 6 mm ETW needles

Manufacturing site	Nipro Medical Industries Ltd, Japan Nipro Corporation Ltd, Thailand
Sterilization method	Ethylene Oxide (EtO or EO) sterilization process
Description of the method that will be used to validate the sterilization cycle	The sterilization of NovoFine® 32G 6 mm ETW needles is validated annually according to ISO 11135 – 1:2014 Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
Description of the packaging to maintain the device's sterility	The needle part that is to be inserted in the skin is placed in an outer cap and sealing paper is welded onto the outer cap. The combination of outer cap and sealing paper maintain sterility until usage
If the sterilization involves ethylene oxide (EO), the maximum levels of residuals.	Maximum level according to ISO 10993-7
If the product is labeled "pyrogen free", a description of the method used to make this determination, e.g., limulus amebocyte lysate (LAL)	The LAL test of NovoFine® needles are made according to United States Pharmacopoeia, USP, Chapter <161> "Bacterial Endotoxin Test" with the limit ≤ 20 EU/device.
Sterility Assurance Level (SAL)	The SAL will be 10^{-6}.
In case of radiation sterilization, the radiation dose	NA

Endotoxin testing is conducted on every batch of the NovoFine® 32 G Tip (0.23/0.25) X 6 mm ETW (extra thin wall), with sample sizes and methods listed in USP general Chapter <161>, that includes and directs to the Bacterial Endotoxin test USP Chapter <85>.

(7) Technological Characteristics:

The NovoFine® 32 G Tip 6 mm ETW needle is considered substantially equivalent to the NovoFine® 32G Tip 6 mm ETW cleared under K062500 and K090111 in intended use, technology, principles of operation, materials and performance. The physical design is identical and only the data that are needed to evaluate substantial equivalence are included. The only modification to the predicate device was to include an additional drug name in the intended use. Because the device is physically identical, biocompatibility and sterility data are only described briefly here.

(8) Non-Clinical Tests Performed:

The NovoFine 32G Tip 6mm ETW needle was tested for compatibility with semaglutide injector (Ozempic) per ISO 11608-2.

Biocompatibility standards ISO 10993-11:1993, ISO 10993-10:2002, ISO 10993-05, ISO 10993-04, including cytotoxicity were followed.

Summary

The purpose of this Design Verification Test report is to verify the functional compatibility between NovoFine® and DV3326 PDS290 semaglutide pen-injector variants according to clause 11 in ISO 11608-2:2012 (1). Compatibility testing according to clause 11 in ISO 11608-2:2012 (1) is covered by specified torque values for assembly, determination of dose accuracy and specified torque value for removal. This verification report documents tests performed according to the DVT protocol of compatibility of the DV3326 PDS290 semaglutide and NovoFine® (2).

The scope is:

- NovoFine® Portfolio:
- 30G (0.30) x 8mm
- 31G (0.25) x 6mm
- 32G (0.23/0.25) x 6mm
- 32G (0.23/0.25) x 4mm

- All four variants of the DV3326 PDS290 semaglutide pen-injector:
- Variant 1: 0.25 mg/0.5 mg/1.0 mg
- Variant 2: 1.0 mg
- Variant 3: 0.25 mg/0.5 mg
- Variant 4: 1.0 mg, 3 ml

The compatibility testing was performed with NovoFine® 32G (0.23/0.25) x 6mm and DV3326 PDS290 semaglutide pen-injector variant 1 and variant 3.

The NovoFine® 32G (0.23/025 mm) x 6mm is representative for the NovoFine® Portfolio based on the following:

- There is no difference in the pen-injector interface of the pen needle (needle thread and the length of the back end needle) for all NovoFine® needle variants.
- Flow resistance is proportional with the length of the needle and inverse proportional with the inner diameter of the needle; hence in regard to dose accuracy, NovoFine® 32Gx6 mm is considered the worst case needle and selected for test of compatibility.

Demonstrated compatibility between NovoFine® 32G (0.23/0.25 mm) x 6mm and the identified DV3326 PDS290 semaglutide pen-injector applies for the entire NovoFine® Portfolio.

The compatibility testing for variant 2 and variant 4 are covered by the test results from variant 1. The rationales of the compatibility test results for variant 1 cover variant 2 and variant 4 are that all variants 1, 2 and 4:

- have identical maximum dose stop at 74 increments (corresponding to 0.740 ml and 1.0 mg semaglutide) and therefore these variants are assessed to have identical high dose volume for the dose accuracy test
- have identical needle interface hub design on the cartridge holder and therefore these variants are assessed to have identical hub assembly and removal characteristics and properties

The differences among variant 1, 2 and 4 are limited to cartridge size (1.5 ml versus 3 ml) and the scale drum imprints. Variant 2 and 4 do not have low dose volume due to that variant 2 and 4 are fixed dose device. These differences are assessed to have no influence on the compatibility test results. Therefore, variant 1 compatibility test results are considered sufficient to cover variant 2 and variant 4.

Following materials were used for the compatibility verification:
NovoFine® 32G (0.23/025 mm) x 6mm batch 16F16S
DV3326 PDS290 semaglutide pen-injector variant 1 (0.25 mg/0.5 mg/1.0 mg) batch GV40055
DV3326 PDS290 semaglutide pen-injector variant 3 (0.25 mg/0.5 mg) batch GV40037

120 pen needles (60 pen needles subsequent to low dose and 60 pen needles subsequent to high dose) were tested for each pen-injector variant and no rejections occurred in regard to the stated parameters and tolerances for assembly torque, dose accuracy and removal torque.

It is concluded that NovoFine® is functional compatible with DV3326 PDS290 semaglutide pen-injector variants in accordance with clause 11 in ISO 11608-2:2012 (1).

(9) Clinical Tests Performed:

No clinical tests are required.

(10) Conclusion drawn from the non-clinical and clinical tests:

Based on the design equivalency and the functional testing, the NovoFine® 32 G Tip 6 mm ETW is substantially equivalent to NovoFine® 32G Tip 6 mm ETW cleared under K062500 and K090111 which is currently marketed in the United States. The only modification to the predicate device was to include an additional drug name in the intended use.