December 19, 2020

Novo Nordisk Inc.
Hiral Shah
Associate Manager, Regulatory Affairs
P.O Box 846
Plainsboro, New Jersey 08536

Re: K202005
Trade/Device Name: NovoFine Plus 32G Tip x 4 mm
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: November 23, 2020
Received: November 25, 2020

Dear Hiral Shah:

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,

Rumi Young
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
NA

Device Name
NovoFine® Plus 32 G 4 mm

Indications for Use *(Describe)*
Indications for Use: NovoFine® Plus 32 G 4 mm needles are intended for use with pen injector devices for the subcutaneous injection of drugs.

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.

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Traditional 510(k)

NovoFine® Plus 32G 4 mm needle

Section 5 Summary

Author
Regulatory Affairs
Novo Nordisk Inc.

Table of contents

Page

510(k) Summary

21 CFR 807.87(h)

As required by 21 CFR 807.92(a)

Date Prepared: December 18, 2020

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92. The NovoFine® Plus 32 G 4 mm needle meets all applicable product and quality standards for hypodermic single lumen needle products.

1 Submitter's Name and Address:

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

Contact Person:
Hiral Shah Palkhiwala
Associate Manager, Regulatory Affairs
Tel: 609-787-7603
Email: hpaw@novonrdisk.com

2 Name of Device:

Proprietary Name:	NovoFine® Plus 32 G 4 mm
Common or usual name:	Pen Needle
Classification:	Class II device; 21 CFR 880.5570, (hypodermic single lumen needle)
Product Code:	FMI (hypodermic single lumen needle)

3 Substantial Equivalence:

Predicate Device: NovoFine® Plus 32 G 4 mm ETW cleared under K133738 on May 21, 2014.

The main purpose of this submission is to provide clarification to the intended use which is similar amongst the cited predicate device.

Additionally, following minor changes have been implemented between the subject device and the predicate NovoFine Plus.

a. Tighten specification for minimum inner diameter of the cannula
b. Change in hub and inner cap polypropylene sub-type
c. Addition of Contract Manufacturing facility
d. Addition of packaging configurations (4 needles (trade) and 6 needles (trade and sample))

The above changes do not affect intended use, indications for use, technological characteristics, the general type of materials, principle of operation, shelf life, and biocompatibility. Therefore, NovoFine® Plus that is the subject of this 510(k) is considered substantial equivalent to the NovoFine® Plus cleared on May 21, 2014, 2006 (K133738) the predicate device.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as supplied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statement related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent laws or their application by the court.

4 Device Description:

NovoFine® Plus 32 G 4 mm needle is a sterile single use needle for subcutaneous injection of drugs with a pen injector device. 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.

5 Intended Use:

NovoFine® Plus 32 G 4mm is intended for use with pen injector devices for the subcutaneous injection of drugs.

Comparison with Predicate Devices:

The subject device is considered substantially equivalent in device design, general type of materials, fundamental scientific technology and device performance as the predicate devices (K133738). The purpose of this submission is to provide clarification to the intended use which is similar amongst the cited predicate device. The table below provides a side by side comparison of the subject device compared to its predicate.

Table 1 Side by side comparison of the subject device and predicate device

Features	NovoFine® Plus 32G 4 mm Subject device	NovoFine® Plus 32G 4 mm Predicate device
Parameter		
Marketing status	K202005	K133738
Intended Use	Intended for use with pen injector devices for the subcutaneous injection of drugs	Intended for use with pen injector devices for the subcutaneous injection of drugs, including insulin, GLP-1 analogs, and somatropin.
Product type	Hypodermic single lumen needle	Hypodermic single lumen needle
Durability	5 years from production date	5 years from production date
Biocompatibility	EN ISO 10993-1	EN ISO 10993-1
Reuse	Single use	Single use
Labeling	See Section 13: Proposed Labeling Labeling configuration: 100 needles (trade) 7 needles (sample) 6 needles (trade and sample) 4 needles (trade)	See Section 13: Proposed Labeling Labeling configuration: 100 needles (trade) 7 needles (sample)
Specifications		
Outer diameter, tip	0.22-0.25 mm	0.22-0.25 mm
Outer diameter, cylindrical part	0.25-0.27 mm	0.25-0.27 mm
Inner diameter	Minimum 0.146 mm	0.145-0.16 mm
Length from hub	4 mm	4 mm
Gauge	32G	32G
Tip configuration	1st and 2nd grinding and glass blasting	1st and 2nd grinding and glass blasting
Hub/≤needle ≥ bond strength	F_{min} = 11.2 N	F_{min} = 11.2 N
Materials		
Hub	Polypropylene (PP) with PE white master batch Color: White	Polypropylene (PP) with PE white master batch Color: White
Cannula	Stainless steel AISI / SUS 304 DIN-kurzname: X 5 CrNi 18 10*	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	Polypropylene (PP) Color: Transparent	Polypropylene (PP) Color: Transparent
Outer needle cap	Polypropylene (PP) Color: Transparent white	Polypropylene (PP) Color: Transparent white
Materials		
Sealing paper	Medical grade paper for steam sterilization	Medical grade paper for steam sterilization
Lubricating oil for patient needle end	Medical grade silicone	Medical grade silicone
Lubricating oil for back needle end	Medical grade silicone	Medical grade silicone

6 Technological Characteristics:

The NovoFine® Plus needle is considered substantially equivalent to the predicate NovoFine® Plus disposable needle in intended use, technology, principles of operation, general type of materials and performance. Differences between the devices do not raise any significant issues of safety and effectiveness. For a detailed side by side comparison to the predicate needles cleared by the Agency, please see the table: Comparison to a legally marketed device in the substantial equivalence.

6.1 Non-Clinical Tests Performed:

The NovoFine® Plus needle will be manufactured in accordance with current Good Manufacturing Practices for Medical Devices. Biocompatibility and performance tests have been performed and the results are in compliance with existing domestic and international standards.

The clarification to the intended use of the subject pen needle device, does not introduce critical differences or new risks to the intended use of the device. The proposed clarification reflects current testing practice and aligns with compatibility summary provided in the submission. As part of the Quality System, NovoFine® Plus has been tested for functional compatibility according to ISO 11608-2:2012 with all leading pen injectors available on the market. This testing has shown connectivity to NovoFine® Plus and maintenance of the dose accuracy through the needle of all leading pen-injectors on the market covering different types of drugs. Thus, subject needle device meets requirements for its intended use and supports the proposed clarification.

List of all ISO standards used in non-clinical performance testing (sterility, biocompatibility, and performance):

- ISO 10993-1: 2018 Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process.
- ISO 17665-1: 2006 Sterilization of health care products – Moist heat-Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 11608-2: 2012 Needle-based injection systems for medical use - Requirements and test methods -- Part 2: Needles
- ISO 9626: 2016 Stainless steel needle tubing for the manufacture of medical devices

6.2 Clinical Tests Performed:

No clinical tests are required.

6.3 Conclusion drawn from the non-clinical and clinical tests:

Based on the design equivalency and the functional testing, Novo Nordisk has determined that the NovoFine® Plus is substantially equivalent to predicate NovoFine Plus , K133738, which are currently marketed in the United States. Differences between the devices do not raise any significant issues of safety and effectiveness.