June 23, 2021
Novo Nordisk Inc.
Hiral Shah
Associate Manager, Regulatory Affairs
P.O Box 846
Plainsboro, New Jersey 08536

Re: K210258
Trade/Device Name: NovoFine
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: FMI
Dated: May 21, 2021
Received: May 24, 2021

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,

For 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)*
K210258

Device Name
NovoFine®

Indications for Use *(Describe)*
NovoFine® 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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K210258 510(k) Summary

As required by 21 CFR 807.92(a)

Date Prepared: June 23, 2021

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92. The NovoFine® needle portfolio 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 Palkhiwala Shah
Manager, Regulatory Affairs
Tel: 609-787-7603
Email: hpaw@novonordisk.com

2 Name of Device:

Trade Name:	NovoFine®
Common or usual name:	Pen Needle
Classification:	Class II device;
Regulation Name:	Hypodermic single lumen needle
Regulation Number:	21 CFR 880.5570
Product Code:	FMI (hypodermic single lumen needle)
Predicate Device	K173479, NovoFine® 32G Tip (0.23/0.25) x 6 mm ETW (extra thin wall)

3 Substantial Equivalence:

Predicate Device: NovoFine® 32G Tip (0.23/0.25) x 6 mm ETW (extra thin wall) (K173479, cleared January 17, 2018)
The main purpose of this submission is to expand the indications for use, which is not restricted to the drugs listed in the predicate device's indications for use.

Additionally, following minor changes have been implemented between the subject device and the predicate NovoFine®:32G Tip (0.23/0.25) x 6 mm ETW (extra thin wall) (K173479, cleared January 17, 2018)

a. Addition of the additional NovoFine® needle variants (30 G 8mm, 31 G 6mm and 32 G 4mm)

b. Tightened specification for minimum inner diameter of the cannula for 32G

The above changes do not affect intended use, materials, principle of operation, shelf life, and biocompatibility. The technological differences do not raise different questions of safety and effectiveness. Additionally, the data demonstrate equivalence and support the indications for use. Therefore, NovoFine® subject of this 510(k) is substantial equivalent to NovoFine® 32G Tip (0.23/0.25) x 6 mm ETW (extra thin wall cleared on January 17, 2018) (K173479) the predicate device.

4 Device Description:

NovoFine® 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.

The device has demonstrated compatibility with the following pen injectors: Autopen® 24, Autopen® Classic, BerliPen® 302, BerliPen® aero 2, Byetta® Pen, ClickStar®, FlexPen® Levemir, FlexPro® 5mg, FlexPro® 15mg, FlexTouch® NovoRapid, HumaPen® LuxuraTM, HumaPen® LuxuraTM HD, InnoLet®, KwikPen®, NordiFlex® 15 mg, NordiPen® 15mg, NovoPen Echo®, NovoPen® 4, NovoPen® 5, Ozempic® (0.25mg/0.5mg/1.0mg), Saxenda®, SoloStar® Lantus, TactiPen®, Victoza® Pen (GLP-1), and Xultophy®.

5 Indication for use:

NovoFine® needles are intended for use with pen injector devices for the subcutaneous injection of drugs.

6 Technological Characteristics:

The NovoFine® is considered substantially equivalent to the predicate NovoFine® disposable needle in intended use, technology, principles of operation, 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 needle cleared by the Agency, please see Table 1.

Comparison with Predicate Devices:

The subject device is considered substantially equivalent in device design, materials, fundamental scientific technology and device performance as the predicate devices (K173479). The purpose of this submission is to expand the indications for use, which is not restricted to the drugs listed in the predicate device's indications for use. 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

	NovoFine® **Subject device**	**NovoFine® 32G Tip (0.23/0.25) x 6 mm** **ETW (extra thin wall) Predicate device**
Parameter		
Marketing status	K210258	K173479
Indication for 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 insulin, liraglutide, semaglutide and somatropin
Product type	Hypodermic single lumen needle	Hypodermic single lumen needle
Shelf life	5 years from production date	5 years from production date
Biocompatibility	Comply with ISO 10993-1 and the following tests were performed - in vitro cytotoxicity intracutaneous reactivity, skin sensitisation, acute systemic toxicity and haemocompatibility (haemolysis)	Comply with ISO 10993-1 and the following tests were performed - in vitro cytotoxicity intracutaneous reactivity, skin sensitisation, acute systemic toxicity and haemocompatibility (haemolysis)
Performance testing	ISO 11608-2: 2012 ISO 9626: 2016	ISO 11608-2: 2012 ISO 9626: 2016
Reuse	Single use	Single use
Labelling	100 needles (trade) 7 needles (sample)	100 needles (trade) 7 needles (sample)
Specifications		
Outer diameter, cylindrical part[2]	0.25-0.27 mm for 31G and 32G 0.298-0.32 mm for 30G	0.25-0.27 mm [1]
Inner diameter[2]	Minimum 0.146 mm for 31G and 32G Minimum 0.165 mm for 30G	0.145-0.16 mm
Length from hub[2]	4 mm for 32G 6 mm for 31G and 32G 8 mm for 30G	4 mm
Gauge[2]	30G 31G 32G	32G
Tip configuration	1st and 2nd grinding and glass blasting	1st and 2nd grinding and glass blasting
Hub/≤needle ≥ bond strength	F_{min} = 22 N	F_{min} = 22 N
Materials		
Hub	Polypropylene (PP) with PE white master batch Color: White	Polypropylene (PP) with PE white master batch Color: White

	NovoFine® Subject device	**NovoFine® 32G Tip (0.23/0.25) x 6 mm ETW (extra thin wall) Predicate device**
Cannula [3]	Stainless steel AISI / SUS 304 DIN-kurzname: X 5 CrNi 18 10 3	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[4]	Gas permeable paper Sterikraft 558 with coating: 5810A	Bactite 60K 43 g/m2 coated with PS-118 laquer 6 g/m2 for ethylene oxide sterilization Color: Light blue (RAL 5012)
Lubricating oil for patient needle end	Medical grade silicone	Medical grade silicone
Lubricating oil for back needle end	Medical grade silicone	Medical grade silicone

[1] By administrative error, the outer diameter and pull force of inner cap from hub were described incorrectly in the predicate 510(k) (K173479) and corrected here.

[2] These differences were assessed by performance testing, and there were no different questions of safety and effectiveness.

[3] In ISO 15510:2014, the name of the stainless-steel material is stated both as X5CrNi-18-9 and X5CrNi-18-10.

[4] The material of the sealing paper is identical between proposed device and predicate device. Only the name of the sealing paper has been changed by the supplier of the sealing paper.

6.1 Non-Clinical Tests Performed

The different indications for use of the subject pen needle device, do not raise different questions of safety and effectiveness compared to the indications for use of the predicate device. The non-clinical performance testing supports the determination of substantial equivalence. NovoFine® 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® and maintenance of the dose accuracy through the needle of all leading pen-injectors on the market covering different types of drugs.

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.
- DS EN/ISO 11607-2:2019 Packaging for terminally sterilized medical devices-Part 2: Validation requirements for forming, sealing and assembly processes
- 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
- Particulates per ISO 11040-4:2015 Prefilled syringes – Part 4: Glass barrels for injectables and sterilized sub assembled syringes ready for filling

Package integrity testing, after environmental conditioning and simulated transportation in accordance with ISTA 3A, was conducted on the final, packaged, and sterile devices. All packaging deemed acceptable for protection of product and sterility maintenance.

The sterilization process and shelf-life for NovoFine® remains the same as the predicate device, K173479. The sterilization method is Ethylene Oxide.

Shelf life of 5 years is validated using the FDA recognized standard ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

7 Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Novofine® is substantially equivalent to the NovoFine® 32G Tip (0.23/0.25) x 6 mm ETW (extra thin wall) with respect to the indications for use, target populations, treatment method, and technological characteristics.