August 25, 2023

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

Re: K231255
Trade/Device Name: NovoFine® Plus
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: August 9, 2023
Received: August 11, 2023

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,

CAPT Alan M. Stevens
Assistant Director
DHT3C: Division of Drug Delivery,
General Hospital, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231255

Device Name
NovoFine® Plus

Indications for Use *(Describe)*
Indications for Use: NovoFine® Plus 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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5 510(k) Summary

21 CFR 807.87(h)

As required by 21 CFR 807.92(a)

(1) Date Prepared: August 25, 2023

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The subject of this Special 510(k) submission is the NovoFine® Plus with gauge 29G, hereafter named 'NovoFine® Plus (subject needle)'. The NovoFine® Plus (subject needle) meets all applicable product and quality standards for hypodermic single lumen needle products. NovoFine® Plus product family will be expanded to include NovoFine® Plus (subject needle).

Submitter's Name and Address

Novo Nordisk Inc.
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Plainsboro, New Jersey 08536

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

(2) Name of Device

Proprietary Name:	NovoFine® Plus
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 32G 4 mm ETW cleared under K202005 on December 19, 2020.

(4) Device Description

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

Mode of operation

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

Intended for use with pen injector devices for the subcutaneous injection of drugs.

Comparison with Predicate Devices

The NovoFine® Plus (subject needle) has the same intended use, indications for use, intended users, basic design, principle of operation, component materials, biocompatibility, shelf life and application of design controls for its development as the NovoFine® Plus cleared under K202005.

Specifically for biocompatibility, an evaluation according to ISO 10993-1:2018 '*Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process*' has been made, which is valid for both the NovoFine® Plus (subject needle) and the NovoFine® Plus cleared under K202005. The evaluation, performed considering all parts of the device having direct or indirect contact with the patient, concludes that NovoFine® Plus does not pose a risk of cytotoxicity, skin irritation, skin sensitisation, material-mediated pyrogenicity, acute or subacute toxicity, genetic toxicity, implantation reactions or any other biological hazard as defined in ISO 10993-1:2018 when used as intended.

In addition, the manufacturing, quality control and clinical evaluation process for the NovoFine® Plus (subject needle) are the same as for the NovoFine® Plus cleared under K202005.

The purpose of this submission is to introduce the 29G gauge needle into the NovoFine® Plus product family, where the predicate device has a 32G gauge needle (see Table 1).

Table 1 Comparison of the characteristics of the NovoFine® Plus (subject needle) and the NovoFine® Plus cleared under K202005 (predicate needle)

Feature	**NovoFine® Plus (subject needle)***	**NovoFine® Plus cleared under K202005 (predicate needle)**
510(k) Number	K231255	K202005
Intended Use	Same as predicate	Intended for use with pen injector devices for the subcutaneous injection of drugs.
Needle Gauge Size (s)	29G	32 G
Needle Length Size (s)	Same as predicate	4 mm
Needle insertion method	Same as predicate	Manual
Provided Sterile	Same as predicate	Sterile - steam

*The NovoFine® Plus product family will include the 32G and 29G gauge needle. Only the 29G gauge needle information is presented in this column

(6) Testing

The subject device NovoFine® Plus (subject needle) has the substantially equivalent technological characteristics as the predicate device NovoFine® Plus cleared under K202005.

Novo Nordisk has verified the design of the subject device as part of its design control process in accordance with the Quality System Regulation. This testing included confirmation of compliance to material and dimension requirements, as per ISO 9626 *Stainless steel needle tubing for the manufacture of medical devices*, and to performance, as per ISO 11608-2: *Needle-based injection systems for medical use – Requirements and test methods– Part 2: Needles*.

The 29G gauge needle does not introduce critical differences or new risks to the intended use of the device.

(7) Conclusion

Based on the design equivalency and the functional testing, Novo Nordisk has determined that the NovoFine® Plus (subject needle) is substantially equivalent to the NovoFine® Plus cleared under K202005, which is currently marketed in the United States. Differences between the devices do not raise any significant issues of safety and effectiveness.