



Food and Drug Administration
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July 31, 2015

Novo Nordisk Inc.
Ms. Poonam Tuliani
Associate Director, Regulatory Affairs
P.O. Box 846
Plainsboro, New Jersey 08536

Re: K150874
Trade/Device Name: NovoPen Echo®
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: June 30, 2015
Received: July 1, 2015

Dear Ms. Tuliani:

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 yours,

 Tina
Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150874

Device Name

NovoPen Echo®

Indications for Use (Describe)

The NovoPen Echo® is a re-useable pen injector designed for single patient use by diabetics for the self-injection of a desired dose of insulin. The pen injector uses PenFill® 3 mL cartridge of NovoLog®, 100 units/mL (U-100) [insulin aspart (rDNA origin) injection] and a single use detachable and disposable pen needle (supplied separately). The pen injector allows the user to dial the desired dose from 0.5 to 30 units in 0.5 unit increments.

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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510(k) Summary K150874

21 CFR 807.87(h)

As required by 21 CFR 807.92(a)

Date Prepared: July 29, 2015

This 510(k) Summary is being submitted in accordance with 21 CFR 807.92.

1. Submitter's Name:

Novo Nordisk Inc.
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Plainsboro, NJ 08536

Contact Person:

Poonam Tuliani
Associate Director, Regulatory Affairs
Tel: 609-786-5210
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2. Device Name:

Proprietary Name: NovoPen Echo[®]
Common Name: Dial-A-Dose Insulin Delivery Device (Pen Injector)
Classification Name: Syringe/Piston (FMF)
Regulation: 21 CFR 880.5860
Class: Class II

3. Substantial Equivalence:

The manufacturing site for NovoPen Echo[®] is to be transferred from Site Device Manufacturing Development (DMD), Denmark to Site Tianjin, China (STJ). Hereinafter, the original cleared device is referred to as NovoPen Echo[®] (DMD) and the modified device is referred to as NovoPen Echo[®] (STJ).

In order to improve manufacturability, production automation, and to align manufacturing with other devices within the NovoPen[®] family, the following changes have been implemented to NovoPen Echo[®].

- Update of software to support manufacturing automation as well as including other minor changes
- Update of selected components and component material changes for a small number of components
- Labelling changes

The above changes do not affect intended use, indications for use, technological characteristics, functionality of components, principle of operation, shelf life, biocompatibility and device user interface. Therefore, NovoPen Echo[®] (manufactured in Novo Nordisk (NN), Site Tianjin, China) is substantially equivalent to Novo Nordisk's NovoPen Echo[®] (manufactured in NN, Site DMD, Denmark), cleared under 510(k) K123766 in August, 2013.

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:

The NovoPen Echo[®] (STJ) is a reusable mechanical pen-injector capable of injecting a dose of up to 30 units of insulin, in 0.5 unit increments, from a PenFill[®] 3 mL cartridge of NovoLog[®], 100 units/mL (U-100) [Insulin aspart Injection (rDNA origin)]. The memory function enables the user of the device to see the quantity of last given dose and hours that have passed since last dose. The operation of the pen-injector for the injection of insulin is entirely independent of the operation of the memory function. The intended dose is mechanically set by rotating a dose button. The insulin is injected by depressing the dose button which via mechanical coupling causes the piston in the insulin cartridge to move forward thereby expelling the intended dose. The device has a memory function and liquid crystal display that allows the user to review the units of the last dose and the number of hours that have elapsed since the last dose was taken. Rotation of the dose button during dose setting causes a sensor to rotate within a coded cylinder. The movement detected by this sensor is stored for later display on the liquid crystal display in the dosage selector module as the

number of units injected. The pen-injector is intended for use with PenFill[®] 3 mL cartridge of NovoLog[®], 100 units/mL (U-100) [Insulin aspart Injection (rDNA origin)] and a single-use, detachable and disposable pen needle (supplied separately by Novo Nordisk). NovoPen Echo[®] (STJ) is substantial equivalent to the primary predicate device NovoPen Echo[®] (DMD)

5. Intended Use including Indication for Use:The Intended Use including Indication for Use for the modified device are as follows:

The Novo Pen Echo[®] is a re-usable pen injector designed for single-patient use by diabetics for the self-injection of a desired dose of insulin. The pen injector uses PenFill[®] 3 mL cartridge of NovoLog[®], 100 units/mL (U-100) [[Insulin aspart Injection (rDNA origin)] and a single use detachable and disposable pen needle (supplied separately). The pen injector allows the user to dial the desired dose from 0.5 to 30 units in 0.5- unit increments.

6. Technological Characteristics:

The NovoPen Echo[®] (STJ) is considered substantially equivalent to the predicate device in intended use, principle of operation, materials, energy source and performance.

The injection technique used to administer insulin is the same as predicate device, NovoPen Echo[®] (DMD). Both devices require a needle to penetrate the subcutaneous layer of tissue, an insulin source and a plunger to push the insulin from the source, through the needle and into the subcutaneous layer of tissue. Both devices are capable of multiple injections from a single insulin source (cartridge).

Both devices have the same 0.5 increment dosing capability and comply with requirements specified in ISO11608-1:2012 Needle-based injection systems for medical use – Requirements and test methods – Part 1: Needle-based injection systems.

As required by 21 CFR 807.92(b)

Testing

Performance Data:

Device Verification Tests were run to verify all product requirements are still met and all changes work properly and complies with the requirements specified in ISO11608-1:2012 Needle-based injection systems for medical use – Requirements and test methods – Part 1: Needle-based injection systems.

Software verification and validation regression testing repeating all static, unit, integration and system, tests as well as additional tests for the changes and related risk control measures was conducted and all tests passed.

Shelf Life:

The NovoPen Echo[®] has an in-use lifetime of 5 years provided that the pen is taken into use within two years of the production date. The NovoPen Echo[®] informs the user via the memory display when the pen has reached its end of life.

Conclusions:

In conclusion, the results of the testing demonstrate that NovoPen Echo[®] (STJ) is as safe and effective and performs as well as the predicate device.

The results of the testing to standards provide additional evidence that NovoPen Echo[®] (STJ) is substantially equivalent to the predicate device, NovoPen Echo[®] (DMD).

The differences between NovoPen Echo[®] (STJ) and the predicate device, NovoPen Echo[®] (DMD), do not raise any new issues of safety or effectiveness.