



November 30, 2023

Bradley Pliskow
Director of R&D and Operations
620 NW Dixie Hwy
Stuart, Florida 34994

Re: K231877

Trade/Device Name: NavaClick Injection System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI, LHI
Dated: September 22, 2023
Received: November 3, 2023

Dear Bradley Pliskow:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, **Juliane C. Lessard -S**

Juliane C. Lessard, Ph.D.
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

Indications for Use

Submission Number (if known)

K231877

Device Name

NavaClick Injection System

Indications for Use (Describe)

The NavaClick Injection System is intended for injection of fluids into the body. It is specifically indicated for injection of botulinum neurotoxin, consistent with the neurotoxin's approved labeling.

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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K231877 510(k) Summary

SUBMITTED BY:

Company Name: Lineage Biomedical.
Address: 620 NW Dixie Hwy
Stuart, FL 34994
Telephone: 1-772-539-9749
Fax: N/A

CONTACT PERSON: Bradley Pliskow
DATE PREPARED: Nov 27, 2023
TRADE NAME: NavaClick Injection System
COMMON and CLASSIFICATION NAME: Piston Syringe
CLASSIFICATION REG/PANEL: 21 CFR 880.5860/ General and Plastic Surgery
PROCEDURE: FMF

PREDICATE DEVICE:

Merit Syringe K171362

DEVICE DESCRIPTION:

The NavaClick Injector is a manually-operated, 1 mL piston syringe consisting of a calibrated, hollow barrel with a standard luer-lock connector into which is inserted a closely-fitted, ratcheted, moveable plunger. The syringe is printed with a graduated scale (1 mL volume), and has audible and tactile feedback upon delivery of each 0.02 mL fluid. The syringe has been designed to enhance the efficiency and precision of neurotoxin injections.

The syringe has been packaged with other components for convenience. The NavaClick Injection System is a kit containing the NavaClick Injectors (syringes), needles, and a vial adapter for delivery of neurotoxin per the labeled indication.

The product is sterile, single use only, non-pyrogenic and sterilized by electron beam radiation.

INDICATIONS FOR USE/INTENDED USE:

The NavaClick Injection System is intended for injection of fluids into the body and is specifically indicated for injection of botulinum neurotoxin, consistent with the neurotoxin's approved labeling.

The general intended use for injection of fluids into the body is identical to that of the predicate device; however, the subject device is not intended for withdrawal of fluids from the body. In addition, the subject device is specifically used to inject botulinum neurotoxin per the neurotoxin product's intended use. This difference does not alter the general intended use of the subject

device for injection of fluids which is identical to a section of the predicate device's intended use statement and covered in 21 CFR 880.5860.

COMPARISON of TECHNOLOGICAL CHARACTERISTICS:

Results from testing based on “Guidance on the Content of Premarket Notification [510(K)] Submissions for Piston Syringes” April 1993, support substantial equivalence of the NavaClick Injector to the predicate Merit Syringe cleared under K171362.

Attribute	NavaClick Injection System (Syringe)	Predicate Device: Merit Syringe K171362	Analysis
Manufacturer	Lineage Biomedical	Merit Medical Systems	
Design	Piston Syringe	Piston Syringe	Same
Device Class	II	II	Same
Procode	FMF	FMF	Same
Syringe Type	Piston Syringe	Piston Syringe	Same
Intended Use	Intended to inject fluids into the body and is specifically indicated for injection of botulinum neurotoxin consistent with the neurotoxin's approved labeling	Used to inject fluids into, or withdraw fluids from, the body	Different The general intended use for injection of fluids is the same for both the subject and predicate device and is covered in 21 CFR 880.5860 (piston syringe). No new questions of safety or effectiveness.
Principle of Operations	Manually operated by advancing and withdrawing the plunger within the barrel	Manually operated by advancing and withdrawing the plunger within the barrel	Same
Specific Drug Use	Neurotoxin	Not specified	Different Injection of botulinum toxin (neurotoxin) is typically achieved using any conventional piston syringe; a specific delivery device is not required or identified in published prescribing information for common botulinum toxin drugs. Therefore, no new questions of safety or effectiveness for use of the NavaClick piston syringe for delivery of neurotoxin.
Design	Standard piston syringe construction. The device uses a two-piece molded ratcheted plunger. Fitting offered with male luer lock connector.	Standard three-piece piston syringe. The device uses a single-piece molded ratcheted plunger. Fitting offered with male luer lock connector	Different The subject device has a free mode (plunger operates freely with no feedback), and a feedback mode (ratchet provides

Attribute	NavaClick Injection System (Syringe)	Predicate Device: Merit Syringe K171362	Analysis
			feedback for incremental delivery). Ratcheted plunger functions the same in both subject and predicate devices to enable incremental volume delivery. There are no new questions of safety or effectiveness.
Materials	The barrel is constructed using polypropylene, the plunger from polypropylene, and the seal from polyisoprene	The barrel is constructed using polypropylene, the plunger from polypropylene, and the seal from silicone.	Different Both polyisoprene and silicone are commonly used plunger seal materials. Testing confirms performance and biocompatibility of subject device. No new questions of safety or effectiveness.
Operational Volume	Operational Volume of 1 mL	Operational volume of 10 mL	Different Use of a plunger within the syringe barrel to move fluid into and out of the syringe for operation of the syringe is the same for both devices. No new questions of safety or effectiveness.
Graduation	Printed with accurate graduation lines that are compliant with ISO 7886-1	Printed with accurate graduation lines that are compliant with ISO 7886-1	Different The subject device has a graduation scale division of 0.1 mL and sub-division of 0.01 mL. Although volume increments for the graduation scale are different, graduation for both the subject and predicate is in compliant with ISO 7886-1. No new questions of safety or effectiveness.
Barrel Transparency	Clear as required by ISO 7886-1	Clear as required by ISO 7886-1	Same
Biocompatibility	Per ISO 10993-1	Per ISO 10993-1	Same
Performance Testing	ISO 7886-1 ISO 80369-7	ISO 7886-1 ISO 594-2 (withdrawn)	Same
Re-use	Single use only	Single use only	Same
Sterilization	Electron Beam	Ethylene Oxide	Different

Attribute	NavaClick Injection System (Syringe)	Predicate Device: Merit Syringe K171362	Analysis
			Both the subject and predicate devices are sterilized using well-established methods. Electron Beam sterilization of the subject device is compliant with ISO 11137-1, ISO 11137-2 and ISO 11137-3. No new questions of safety or effectiveness.
Accessories	Packaged as a kit	Not a kit configuration	Different The NavaClick syringe is packaged with needles and a vial adapter for convenience of the user. The kit components are previously 510k cleared devices to be utilized per the cleared indications. No new questions of safety or effectiveness.

The NavaClick Injector has the same intended use, materials of construction, and principle of operations as the predicate device. There are minor differences between the subject and predicate devices. Although they are both 3-part piston syringes consisting of a barrel, plunger and tip, the Nava device also has grips to enhance control. Both devices have ratcheted plungers; however, the mechanism to produce an audible clicking and tactile feedback is different. The Nava device allows the feedback mechanism to engage or disengage by twisting the thumb rest 90 degrees. These differences are not significant with regard to the function of the syringe to inject fluids; these minor differences do not raise different questions of safety and effectiveness.

Performance Testing

The NavaClick Injection System components described in this summary have been tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 7886-1:2017 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
- ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
- ISO 7864:2016 Sterile hypodermic needles for single use – Requirements and test methods

Biocompatibility Testing

Biocompatibility testing of the predicate device was conducted per ISO 10993-1:2018 and the risk-based approach outlined in FDA guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Sep 4, 2020. Based on the standard, the kit components were defined as externally communicating, limited exposure and either blood path indirect (syringe and adapter) or circulating blood (needle). The following testing was conducted on all kit components and no deviations were noted.

- Cytotoxicity (ISO 10993-5:2009 "Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity")
- Sensitization (ISO 10993-10:2021 "Biological evaluation of medical device – Part 10: Tests for skin sensitization")
- Irritation (ISO 10993-23:2021 "Biological evaluation of medical device – Part 23: Test for irritation")
- Acute Systemic Toxicity (ISO 10993-11:2017 "Biological evaluation of medical device – Part 11: Tests for systemic toxicity")
- Hemolysis (ISO 10993-4:2017 "Biological evaluation of medical device – Part 4: Selection of tests for interactions with blood")
- Material Mediated Pyrogenicity (ISO 10993-11:2017 "Biological evaluation of medical device – Part 11: Tests for systemic toxicity")

Evaluation of particulate in the fluid path per USP <788> has been conducted on the NavaClick Injection System. Although there are no USP specifications for particulate matter found in or on medical devices, by comparison, the kit components met the specification for small volume parenteral fluids.

Results from the biocompatibility testing support the biocompatibility and safety of the subject device.

Sterility and Shelf Life

The sterilization method for the NavaClick Injection System is electron beam irradiation with a sterilization dose minimum of 25kGy. Acceptable test results from the sterilization validation demonstrated the ability of the electron beam process to consistently yield a sterility assurance level (SAL) of 10^{-6} for the NavaClick Injection System. Sterilization validation and endotoxin testing was completed in accordance with the following standards. No deviations were noted.

- ISO 11137-1: 2006/Amd 2:2019 Sterilization of health care products – Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 11137-2: 2013 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

- ISO 11137-3:2017 Sterilization of health care products – Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control
- AAMI TIR29:2012 (R2017) Guide For Process Characterization And Control In Radiation Sterilization Of Medical Devices
- USP <85> Bacterial Endotoxin Test

Accelerated stability testing demonstrates the sterility and performance of the device to support the shelf-life of 1 year.

Product stability testing of the NavaClick Injection System was conducted after accelerated aging per ASTM F1980-21 *Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices*. Product performance testing of each component was conducted according to the relevant ISO standard as well as functional performance testing as a kit.

Package (sterile barrier) testing was performed on the subject device after accelerated aging per ASTM F1980-21 *Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices*. Package testing was also performed after simulated environmental conditioning (ASTM D4332-22) and distribution (ASTM D4169-22). Sterile barrier integrity testing was completed in accordance with the following standards. No deviations were noted.

- Visual inspection (ASTM F1886)
- Bubble Leak Test (ASTM 2096-11)
- Seal Strength (ASTM F88/F88M-21)

Conclusion

Based on the intended use, technological characteristics, performance testing, and biocompatibility studies, the NavaClick Injection System meets the requirements that are considered essential for its intended use. The technological differences between the predicate (K171362) Merit Syringe and the subject device do not raise any new questions of safety or effectiveness. The NavaClick Injection System is considered substantially equivalent to the predicate device.