4/15/2022

Nipro Medical Corporation
Jessica Oswald-Mcleod
Director QARA
3150 NW 107th Ave
Doral, Florida 33172

Re: K212677
Trade/Device Name: aboNT SYRINGE
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI
Dated: March 16, 2022
Received: March 18, 2022

Dear Jessica Oswald-Mcleod:

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 CAPT Alan Stevens
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212677

Device Name
aboNT SYRINGE

Indications for Use *(Describe)*
Indicated for intramuscular administration of Dysport® for the temporary improvement of moderate to severe glabellar lines in adults <65 years of age.

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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510(K) Summary: K212677 aboNT Syringe

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content is provided in conformance with 21 CFR §807.92.

1. 807.92(a)(1) Submitter Identification

Applicant Name:	Nipro Medical Corporation
Applicant Address:	3150 NW 107th Ave. Doral FL 33172 USA
Phone:	+1 305-432-6699
Establishment Registration:	1056186
Contact Person:	Jessica Oswald-McLeod Director, Quality Assurance and Regulatory Affairs
Email:	JessicaO@nipromed.com
Preparation Date:	April 15, 2022

2. 807.92(a)(2) Device Identification

Trade Name:	aboNT Syringe
Common Name:	Disposable syringe with Needle
Classification Name:	piston syringe
Regulation Number:	880.5860, 880.5570
Panel:	General Hospital (80)
Product Code:	FMF, FMI
Regulatory Class:	Class 2

3. 807.92(a)(3) Predicate Identification

   Legally marketed substantial equivalent device: K123710, UniTox® Syringe

4. 807.92(a)(4) Device Description

   The aboNT Syringe is a piston syringe with needle consisting of graduated barrel, plunger rod, and gasket. It is provided with a permanently attached hypodermic needle that is 31G x 5/16". The syringe barrel is 0.3 mL in volume, with a graduated scale labeled in both volumetric (mL) and corresponding unit dosing for Dysport® (60 units/0.3mL). The syringe is sterile, single use only, non-toxic, non-pyrogenic and sterilized by E-beam radiation. The shelf-life has been determined to be 5 years.

5. 807.92(a)(5) Indications for Use

   The aboNT Syringe is indicated for intramuscular administration of Dysport® for treatment of glabellar lines in adults <65 years of age.

6. 807.92(a)(6) Comparison of the technological characteristics

   The syringe is substantially equivalent to the predicate device in the following technological characteristics:

Table 1: Technological Characteristics Comparison

Element of Comparison		Subject Device	Predicate	Discussion of Differences
A)	**Product Description**			
1.	Intended Use	Injection of Dysport	Injection of Botox	Similar – both syringes are intended to be used for administration of botulinum toxin
2.	Indications for Use	The aboNT Syringe is indicated for intramuscular administration of Dysport® for treatment of glabellar lines in adults <65 years of age.	UniTox Syringe is single use, sterile, intended use for the subcutaneous injection of Botox® Cosmetic into parts of body below the surface of skin.	Similar – both syringes are intended to be used for administration of botulinum toxin
3.	Syringe type	Piston syringe with attached needle	Piston syringe with attached needle	Same
4.	Specific drug use	Dysport®	Botox Cosmetic	Similar – both drugs are a neurotoxic protein used to diminish wrinkles.
5.	Design consideration	Permanently attached needle, low-dead space syringe, with specific toxin dose graduation markings	Permanently attached needle, low-dead space syringe, with specific toxin dose graduation markings	Same
6.	Operational Principles	Manual	Manual	Same
B)	**Physical Characteristics**			
1.	volume	0.3mL / 60 units of Dysport	0.5mL / 20 units of Botox	Similar – volume is based on needed treatment.
2.	needle length	5/16”	5/16"	Same
3.	needle gauge	31	30	Similar – does not raise any new issues of safety or effectiveness
4.	needle tip configuration	Single lumen	Single lumen	Same
5.	tip type	Permanently attached needle	Permanently attached needle	Same

Element of Comparison	Subject Device	Predicate	Discussion of Differences
6. needle cover color	Natural	yellow	Similar – does not raise any new issues of safety or effectiveness
C) Dimensional Characteristics (results of testing provided in Exhibit DD)			
1. Length of barrel (mm)	67.55 ± 0.50	Min: 82.675 Max: 82.723	Differences in dimensional characteristics due to volume of syringe. The subject device volume is 0.3mL, compared to the predicate volume of 0.5mL.
2. inner diameter of barrel (mm)	3.00 ±0.05	Min: 3.491 Max: 3.585	
3. outer diameter of barrel (mm)	5.18 ± 0.2	Min: 5.393 Max: 5.454	
4. Gasket - Outer diameter of 1st seal (mm)	3.36 ± 0.05	Min: 3.792 Max: 3.810	
5. Gasket - Outer diameter of 2nd seal (mm)	3.36 ± 0.05	Min: 3.703 Max: 3.724	
D) Biocompatibility			
1. Category	Complaint to ISO 10993-1	Complaint to ISO 10993-1	Same
E) Mechanical and Performance Specifications			
1. barrel transparency -	No particle and extraneous matter	No particle and extraneous matter	Same
2. delivery accuracy	Less than half nominal capacity: Min: 0.0968 mL Max: 0.1024 mL Equal to or greater than half nominal capacity: Min: 0.269 mL Max: 0.300 mL	Less than half nominal capacity: Min: 0.0957 mL Max: 0.1008 mL Equal to or greater than half nominal capacity: Min: 0.485 mL Max: 0.496 mL	Both devices within specification
3. reuse durability	NA – single use only	NA – single use only	Same
4. needle cover strength	Min: 0.32 kgf Max: 0.51 kgf	Min: 0.52 kgf Max: 1.57 kgf	Both devices within specification
5. hub/needle bond strength	Min: 44.72 N	Min: 42.65 N	Both devices within specification
F) Sterilization			

Element of Comparison	Subject Device	Predicate	Discussion of Differences
1. Method	E-Beam	EtO	Similar – no new issues of safety and effectiveness
2. Shelf-life	5 years	5 years	Same

7. 807.92(a)(6) Substantial Equivalence

The subject device is substantially equivalent in fundamental design, function, device materials, operating principle, intended use and technology as the legally marketed predicate device. The differences between the devices are due to the administration of a similar specific drug; this drug determines the requirements of the syringe graduation scale markings, syringe volume, and needle gauge.

Testing confirms that these differences do not raise any issues of safety and effectiveness. The aboNT Syringe meets specifications equivalent in design and technological characteristics to the predicate device.

The subject device complies with all applicable voluntary consensus standards for performance, biocompatibility, packaging, transportation, and sterilization. This testing supports the claims of substantial equivalence to the predicate device.

8. 807.92(b)(1) Summary of Non-clinical tests

Non-clinical tests performed are outlined below. All tests were performed within the specifications of the standards listed.

a. Visual Inspection
   - ISO 7886-1 Second edition 2017-05 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
   - ISO 7864 Fourth edition 2016-08-01 Sterile hypodermic needles for single use - Requirements and test methods)

b. Dimensional Specifications
   - ISO 7886-1 Second edition 2017-05 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use

c. Mechanical and Performance Characteristic
   - ISO 7886-1 Second edition 2017-05 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
   - ISO 7864 Fourth edition 2016-08-01 Sterile hypodermic needles for single use - Requirements and test methods
   - ISO 8537 Third edition 2016-03-15 Sterile single-use syringes, with or without needle, for insulin.
   - ISO 11608-1 Third edition 2014-12-15 Needle-based injection systems for medical use - Requirements and test methods - Part 1: Needle-based injection systems

d. Chemical and biological characteristic
   - ISO 7886-1 Second edition 2017-05 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
   - ISO 8537 Third edition 2016-03-15 Sterile single-use syringes, with or without needle, for insulin.

e. Sterilization validation
   - ISO 11137-1 First edition 2006-04-15 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013) and Amendment 2 (2018)]

- ISO 11137-2 Third edition 2013-06-01 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- ISO 11137-3 Second edition 2017-06 Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation, and routine control

f. Shelf-life testing
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices Transportation tests
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems

g. Dye Penetration and Seal Strength testing
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F88/F88M-1 Standard Test Method for Seal Strength of Flexible Barrier Materials

h. Biocompatibility and Chemical Characterization
- ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
  1. Cytotoxicity: MEM Elution
  2. Sensitization: Kligman Maximization
  3. Intracutaneous Irritation
  4. USP Rabbit Pyrogen Study, Material Mediated
  5. Extractables and Leachables

i. Particulate Matter
- USP <788> Particulate Matter in Injections

9. 807.92(b)(2) Summary of Clinical Testing

   This submission does not warrant any clinical testing, therefore no clinical testing performed for or provided in this submission.

10. 807.92(b)(3) Conclusions drawn from non-clinical and clinical tests.

    The aboNT Syringe is identical to the predicate in intended use, device operation, and functional capabilities. Due to the difference in specific drug, minor differences exist in the indications for use, and model configuration. These differences do not pose any new risks to the safety and effectiveness of the device.

    Internal verification and validation testing confirms the subject device specifications are met, and the testing results support the claims for biocompatibility, shelf life, sterilization, and functional testing according to Recognized standards.

    The testing results of non-clinical testing and comparison of technological characteristics with the predicate device demonstrate that the aboNT Syringe performs equivalent to the predicate device when used as intended.