May 25, 2023

Nipro Medical Corporation
Jessica Oswald-Mcleaod
Director, Quality and Regulatory
3150 NW 107th Ave.
Doral, Florida 33172

Re: K222852
Trade/Device Name: Nipro SafeTouch Needle; Nipro SafeTouch Needle with Syringe
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: April 25, 2023
Received: April 28, 2023

Dear Jessica Oswald-Mcleaod:

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,

Courtney Evans -S

Digitally signed by Courtney Evans -S
Date: 2023.05.25 15:33:54 -04'00'

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)*
K222852

Device Name

Nipro SafeTouch Needle; Nipro Syringe with SafeTouch Needle

Indications for Use *(Describe)*

The Nipro SafeTouch Needle is indicated for general purpose injection and aspiration of fluid from vials, and to and from parts of the body below the surface of the skin. It includes a needle shield to prevent against accidental needlestick injuries. The needle is compatible with standard Luer-lock syringes.

The Nipro Syringe with SafeTouch Needle is indicated for general purpose injection and aspiration of fluid from vials, and to and from parts of the body below the surface of the skin. It includes a needle shield to prevent against accidental needlestick injuries.

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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K222852
510(K) Summary

Prepared on: May 23, 2023

1. Contact Details - 21 CFR 807.92(a)(1)

Applicant Name:	Nipro Medical Corporation, North America division
Applicant Address:	3150 NW 107th Ave. Doral FL 33172 USA
Establishment Registration:	1056186
Contact Person:	Jessica Oswald-McLeod Director, Quality and Regulatory
Phone:	1-305-432-6699
Email	JessicaO@nipromed.com

2. Device Name - 21 CFR 807.92(a)(2)

Trade Name:	Nipro SafeTouch Needle Nipro Syringe with SafeTouch Needle
Common Name:	Disposable Syringe with Safety Needle
Classification Name:	Piston syringe, Hypodermic single lumen needle
Regulation Number:	880.5860, 880.5570
Panel:	General Hospital (80)
Product Code:	FMF, FMI
Regulatory Class:	Class 2

3. Legally Marketed Predicate Device - 21 CFR 807.92(a)(3)

K162081: BD 1mL Luer-lok Hypodermic Syringe with BD Eclipse Hypodermic Needle

4. Device Description Summary - 21 CFR 807.92(a)(4)

The Nipro SafeTouch Needle is a disposable hypodermic single lumen needle with attached safety device. The safety device is a needle shield that covers the needle post treatment eliminating accidental needlestick injuries. It is provided with and without a piston syringe.

The Nipro SafeTouch Needle is available in gauges of 18-30, lengths of ½" to 1 ½". The needles are available individually or attached to a luer lock syringe in volumes of 1, 3, 5 and 10mL.

4.1 Nipro Syringe with SafeTouch Needle Configurations

Syringe Volume (mL)	Needle Gauge	Needle Length (inches)
1	25	5/8
	27	1/2
	30	1/2
3	25	1/2 1
	23	1
	22	1 1-1/4
	21	1 1-1/2
	20	
	18	
5	22	
	21	
	20	
10	22	
	21	
	20	

4.2 Nipro SafeTouch Needle Configurations

Needle Gauge	Needle Length (inches)
18	1 1-1/2
19	
20	
21	
22	3/4
	1
	1-1/2
23	1
	1-1/2
25	5/8
	1
	1-1/2

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Needle Gauge	Needle Length (inches)
26	1/2
27	1/2
	1 1/4
30	1/2

The device is sterile, single use only, non-toxic, and non-pyrogenic. It is sterilized by Ethylene Oxide gas and has a shelf-life of 5 years.

The Nipro Syringe with SafeTouch Needle is identical to the reference device, K944355 Nipro Disposable Syringes and Needles, in terms of manufacturing and sterilization methods and facilities and materials of construction. This submission is to add the safety shield to the hypodermic needle and market it independently as well as attached to a Nipro luer-lock syringe.

5. Intended Use/Indications for Use - 21 CFR 807.92(a)(5)

The Nipro SafeTouch Needle is indicated for general purpose injection and aspiration of fluid from vials, and to and from parts of the body below the surface of the skin. It includes a needle shield to prevent against accidental needlestick injuries. The needle is compatible with standard Luer-lock syringes.

The Nipro Syringe with SafeTouch Needle is indicated for general purpose injection and aspiration of fluid from vials, and to and from parts of the body below the surface of the skin. It includes a needle shield to prevent against accidental needlestick injuries.

6. Technology Comparison - 807.92(a)(6)

The subject device is identical to the predicate device in operational mode, physical construction, and intended use. Both devices contain a mechanism that requires physical action by the clinician to cover the needlepoint after use protecting against accidental needlesticks. Once activated, the safety cannot be deactivated.

They are provided sterile with a 5-year shelf-life and are for single use only. They have the same patient contact and duration.

Item for Comparison	Subject device: K222852 SafeTouch Needle / Syringe with SafeTouch Needle	Predicate device: K162081 BD Luer-Lok™ Hypodermic Syringe with BD Eclipse™ Hypodermic Needle	Conclusion
1. Device Description			
1.1. Indications for Use	The Nipro SafeTouch Needle with syringe is indicated for general purpose injection and aspiration of fluid to	The BD 1mL Luer-Lok™ Hypodermic Syringe with BD Hypodermic Needle or BD Eclipse™	Similar – no new issues of safety and effectiveness

Item for Comparison	Subject device: K222852 SafeTouch Needle / Syringe with SafeTouch Needle	Predicate device: K162081 BD Luer-Lok™ Hypodermic Syringe with BD Eclipse™ Hypodermic Needle	Conclusion
	and from parts of the body below the surface of the skin. It includes a needle shield to prevent against accidental needlestick injuries.	Hypodermic Needle is intended for use by health care professionals for general purpose injection and aspiration of fluid from vials, ampoules, and parts of the body below the surface of the skin. The BD Eclipse™ Hypodermic Needle contains a mechanism that covers the needlepoint after use. In the activated position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/ syringe combination.	
1.2. Mechanism of Action	Mechanical/Manual	Mechanical/Manual	Same
1.3. Technology Overview	Graduated disposable piston syringe provided with a safety hypodermic needle consisting of a Stainless-Steel cannula with plastic hub and needle shield.	Graduated disposable piston syringe provided with a safety hypodermic needle consisting of a Stainless-Steel cannula with plastic hub and needle shield.	Same
1.4. Anatomical Location	intramuscular, intravascular, or subcutaneous injection	intramuscular, intravascular, or subcutaneous injection	Same
2. Components and Materials of Construction			

Item for Comparison	Subject device: K222852 SafeTouch Needle / Syringe with SafeTouch Needle	Predicate device: K162081 BD Luer-Lok™ Hypodermic Syringe with BD Eclipse™ Hypodermic Needle	Conclusion
2.1. Syringe barrel	Polypropylene	Styrene acrylic copolymer	Similar – no new issues of safety and effectiveness
2.2. Lubricant	Silicone	Silicone	Same
2.3. Plunger	Polypropylene	Polypropylene	Same
2.4. Stopper	Polyisoprene Rubber	Polyisoprene Rubber	Same
2.5. Needle Cannula	Stainless Steel	Stainless Steel	Same
2.6. Needle Hub with integrated safety mechanism (needle shield)	Polypropylene	Polypropylene	Same
3. Physical Characteristics			
3.1. Needle Gauge	18 - 30	20 - 30	Nipro provides a larger gauge needle. Testing results demonstrate no new issues of safety and effectiveness
3.2. Needle hub Color	The needle hub is color-coded to the appropriate gauge needle per ISO 6009	The needle hub is color-coded to the appropriate gauge needle per ISO 6009	Same
3.3. Needle Length	½" - 1 ½"	½" - 1	Nipro provides a longer length needle. Testing results demonstrate no new issues of safety and effectiveness
3.4. Syringe Volume	1 – 10 mL	1-10mL	Same
4. Sterility			
4.1. Method	EO	Gamma	Both methods are recognized as Category A.
4.2. Single-Use	yes	yes	Same
4.3. SAL	10^{-6}	10^{-6}	Same

Item for Comparison	Subject device: K222852 SafeTouch Needle / Syringe with SafeTouch Needle	Predicate device: K162081 BD Luer-Lok™ Hypodermic Syringe with BD Eclipse™ Hypodermic Needle	Conclusion
4.4. Shelf Life	5 years	5 years	Same
5. Biological Specifications			
5.1. Systemic Injection	No abnormalities or mice death	No abnormalities or mice death	Within Criteria; Same
5.2. Intracutaneous reaction test	No erythema, edema, or necrosis	No erythema, edema, or necrosis	Within Criteria; Same
5.3. Hemolysis test	Hemolytic index shall not exceed 2%	Hemolytic index shall not exceed 2%	Within Criteria; Same
5.4. Bacterial Endotoxin	<= 20 EU/device	<= 20 EU/device	Within Criteria; Same
5.5. Microbial barrier test	No microbial growth was observed	No microbial growth was observed	Within Criteria; Same

7. Non-Clinical and/or Clinical Tests Summary and Conclusions – 21 CFR 807.92(b)

The submitted performance testing is representative of the functional testing that is performed at final inspection and testing during routine manufacturing. Bench testing was performed on the subject device and the predicate device. The following standards were used. No deviations were noted.

a. Visual Inspection (ISO 7886-1, ISO 7864, ISO 6009)
b. Dimensional Specifications (ISO 7886-1, ISO 7864, ISO 80369-7)
c. Mechanical and Performance Characteristic (80369-7, ISO 23908, ISO 9626, ISO 7886-1, ISO 7864, ISO 9626)
d. Chemical Specifications (ISO 7886-1, ISO 7864)
e. Sterilization (ISO 11607-1, ISO 11607-2, ISO 11135, USP <71>, USP <55>)
f. Shelf-life testing (ASTM F1980-07)
g. Packaging and Transportation tests (ASTM D4169-16)
h. Dye Penetration packaging tests (ASTM F1929-15)
i. Biocompatibility and Chemical Characterization (ISO 10993-1)
   - Cytotoxicity: MEM Elution (ISO 10993-5)
   - Systemic Toxicity: Systemic Injection (ISO 10993-11)
   - Sensitization: Guinea Pig Maximization (ISO 10993-10)
   - Irritation: Intracutaneous Reactivity (ISO 10993-23)
   - Pyrogenicity:

  - Bacterial Endotoxin (BET) (ANSI/AAMI ST72:2011/(R)2016, USP-NF M98910_01_01 <161>, USP-NF M98830_02_01 <85>,)
  - Material mediated (USP-NF<151>)
- Hemocompatibility: Hemolysis (indirect) and Direct contact (ISO 10993-4 and ASTM F756)
- Sterilization Residuals: EO/ECH Residuals (ISO 10993-7)
- Particulates Testing: Sizing and counting Particulates: Light Obscuration Method (USP <788>)

A simulated clinical study was performed according to FDA Guidance, Medical Devices with Sharps Injury Prevention Features. Five hundred (500) subject devices were evaluated across 10 trained professionals. There were no device failures, no user-related adverse events or safety device related adverse events.

Internal verification and validation testing confirms that the SafeTouch Needle with or without Syringe meets specifications equivalent in design and technological characteristics to the predicate device.

8. Conclusion Statement

The SafeTouch Needle with or without Syringe complies with all applicable voluntary consensus standards for performance, biocompatibility, packaging, transportation, and sterilization. Through functional performance testing the subject devices have demonstrated substantial equivalence to the predicate device.