October 9, 2019

Nipro Medical Corporation
Jessica Oswald-Mcleod
Director, QA/RA
3150 NW 107th Ave.
Doral, Florida 33172

Re: K191359
Trade/Device Name: Nipro Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI
Dated: September 4, 2019
Received: September 9, 2019

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 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K191359

Device Name
Nipro Syringe

Indications for Use *(Describe)*
To inject fluids into or withdraw fluids from the body.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary: K191359

1. Submitter Information
   Nipro Medical Corporation
   3150 NW 107th Ave.
   Doral FL 33172
   Tel: 305-599-7174
   Establishment Reg.: 1056186
   Contact Person: Jessica Oswald-McLeod, Director QARA

2. Date of Preparation: October 7, 2019

3. Identification of Predicate: K173029: Nipro Disposable Syringes

4. Identification of Subject Device
   a. Regulation Name: Piston syringe
   b. Regulation Number: 880.5860
   c. Product Code: FMF
   d. Common Name: Syringe, Piston
   e. Trade Name: Nipro Syringe

5. Device Description
   The NIPRO Syringe is a piston syringe consisting of graduated barrel, plunger rod, and gasket. It is provided in luer slip, luer lock and eccentric luer slip tips, with and without attached hypodermic needles. Needles are available in ranges of 20-27G, and 3/8 to 1 ½" in length. Gauges are color coded for easy differentiation. Its function is mechanical. The syringe is sterile, single use only, non-toxic, non-pyrogenic and sterilized by Ebeam radiation. The shelf-life has been determined to be 5 years.

| Syringe size (volume, mL) | Gauges | Needle Lengths/tip | Wall |
|---|---|---|---|
| **1** | 25-27G | 3/8" – 5/8" | 25G: thin<br>26-27G: regular |
| | Without needle | Luer lock and luer slip tip | NA |
| **3** | 20-25 | 5/8" – 1 ½" | thin |
| | Without needle | Luer lock and luer slip tip | NA |
| **5** | 20-25 | 1 – 1 ½" | thin |
| | Without needle | Luer lock and luer slip tip | NA |
| **10** | 20-22 | 1 – 1 ½" | thin |
| | Without needle | Luer lock and luer slip tip | thin |
| **20** | Without needle | Luer lock and eccentric slip tip | NA |

| Syringe size (volume, mL) | Gauges | Needle Lengths/tip | Wall |
|---|---|---|---|
| **30** | Without needle | Luer lock and eccentric slip tip | NA |
| **50** | Without needle | Luer lock and eccentric slip tip | NA |

6. Indications for Use Statement

| Characteristics | Subject Device | Primary Predicate |
|---|---|---|
| **Indication for Use** | to inject fluids into or withdraw fluids from the body | to inject fluids into or withdraw fluids from the body |
| **Prescription Only or Over the counter** | Prescription | Prescription |

*Discussion of Differences*

The indications for use are the same. However, the labeling was updated from ≥2 years old to adult and pediatric with no restrictions on age.

7. Summary of Technological Characteristics

**Table 5A- Technological Comparison with the Predicates**

| Element of Comparison | Subject device | Predicate device |
|---|---|---|
| Patient population | Adult and pediatric | 2 years old and above |
| Materials | • Polypropylene<br>• Elastomer<br>• Stainless steel | Same |
| Design: Operational mode | Mechanical | Same |
| Design: Physical characteristics | • Hollow graduated barrel<br>• Plunger rod<br>• gasket | Same |
| Design: Device Configurations | • Luer lock<br>• Luer slip<br>• Eccentric tip<br>• With needle<br>• Without needle | Same |
| Intended Use | to inject fluids into or withdraw fluids from the body | Same |
| Sterilization Method | Ebeam Radiation | Same |
| Expiry dating | 5 years | Same |
| Energy Source | NA | Same |

| Element of Comparison | Subject device | Predicate device |
|---|---|---|
| Syringe size | 1cc, 3cc, 5cc, 10cc, 20cc, 30cc, 50cc | Same |
| Needle length | 3/8 to 1 ½ inch | Same |
| Needle gauge | 20-27G | Same |

*Discussion of Differences*

The technological characteristics are the same because the device is the same. However, because of changes to the labeling chemical characterization and a toxicological risk assessment was provided. Non-clinical performance testing was conducted to support substantial equivalence.

8. Non-Clinical Performance Testing

   a. Biocompatibility (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (2009/Technical Corrigendum 1 2010)
      i. Cytotoxicity: MEM Elution (ISO 10993-5:2009)
      ii. Sensitization: Kligman Maximization (ISO 10993-10: 2010)
      iii. Intracutaneous Irritation (ISO 10993-10: 2010)
      iv. ISO Acute Systemic Toxicity Study in Mice (ISO 10993-11: 2006)
      v. USP Rabbit Pyrogen Study, Material Mediated (USP 39-NF34: 2016, <151> and ISO 10993-11: 2006)
      vi. ASTM Hemolysis Study (ASTM F756:2013)
      vii. USP Limulus Amebocyte Lysate (LAL) testing, Kinetic-Chromogenic Method (USP 39-NF34: 2016, <85> and <161>)
      viii. Particulate Analysis – Device fluid pathway (USP 39-NF34: 2016, <788>)

Other non-clinical tests were conducted to verify that the Nipro Syringe met all design specifications and is Substantially Equivalent (SE) to the predicate. The test results demonstrated that the Nipro Syringe complies with the following standards:

   b. Visual Inspection (ISO 7886-1, ISO 7864-1)
   c. Dimensional Specifications (ISO 7886-1)
   d. Gauging (ISO 594-1)
   e. Mechanical and Performance Characteristic (ISO 7886-1, ISO 7864-1, ISO 594-1, ISO 594-2)
   f. Chemical and biological characteristic (ISO 7886-1, ISO 11137-1)
   g. Sterilization validation (ISO 11137-1, ISO 11137-2, ISO 11137-3)
   h. Transportation tests (ASTM-D4169-09)
   i. Pyrogen testing (ISO 10993-11, USP 39-NF34: 2016, <151>)
   j. Shelf-life testing (ASTM F1980-07)

k. Chemical Characterization (ISO 10993-17:2002)
l. Toxicological Risk Assessment (ISO 10993-18: 2005)

9. Clinical Test Conclusion
   No clinical Study is included in this submission

10. Substantially Equivalent (SE) Conclusion
    The evaluation of the subject device performance demonstrates that it is as safe and as effective as the legally marketed predicate devices.