March 24, 2026

Nipro Medical Corporation
Jessica Oswald-Mcleod
Director, Regulatory Affairs
3150 NW 107th Ave.
Miami, Florida 33172

Re: K253047
Trade/Device Name: PRESSONE™
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: February 26, 2026
Received: February 26, 2026

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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Shruti N. Mistry -S

Shruti Mistry
Assistant Director, Injection Devices
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253047

Device Name
PRESSONE™

Indications for Use *(Describe)*
PRESSONE™ is indicated for use with syringes for general purpose fluid injection/withdrawal.

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 - PRESSONE™

Date Created: March 23, 2026

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

Applicant Name	Nipro Medical Corporation
Applicant Address	3150 NW 107th Ave. Miami FL 33172 United States
Applicant Contact Telephone	305-432-6699
Applicant Contact	Mrs. Jessica Oswald-McLeod
Applicant Contact Email	Jessicao@nipromed.com

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

Device Trade Name	PRESSONE™
Common Name	Hypodermic single lumen needle
Classification Name	Needle, Hypodermic, Single Lumen
Regulation Number	880.5570
Product Code	FMI

Legally marketed predicate device (21 CFR 807.92(a)(3))

K070440, BD Hypoint Needle, Product Code FMI

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

PRESSONE™ is a sterile, single-use disposable hypodermic needle designed to deliver or withdraw fluids from the body via a plastic luer- lock hub and single-lumen stainless steel cannula. PRESSONE™ is for prescription use only.

The needle size is 25G x 5/8". It is sterilized by gamma radiation with a shelf-life of 5 years.

Each needle is individually packaged in a hard plastic container and sealed with a label to maintain sterility until the point of use. The case serves as the needle protector.

PRESSONE™ enables fluid transfer through manual pressure applied via a connected syringe or infusion set equipped with an ISO 80369-7 compliant luer-lock hub, for use in standard medical procedures involving fluid administration or withdrawal.

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

PRESSONE™ is indicated for use with syringes for general purpose fluid injection/withdrawal.

Indications for Use Comparison (21 CFR 807.92(a)(5))

The indications for use are the different from that of the predicate device; However, the intended use of the devices is the same.

Technological Comparison (21 CFR 807.92(a)(6))

Technological Characteristic	Subject device: PRESSONE™	Predicate device: Hypoint	Conclusion
Indications for Use	PRESSONE™ is indicated for use with syringes for general purpose fluid injection/withdrawal.	The BD Hypoint™ Needle is intended for use with syringes and injection devices for general purpose fluid injection / aspiration.	The indications for use are different; however, the intended use of the devices are the same.
Mechanism of Action	Mechanical / manual	Mechanical / manual	Same
Technology Overview	The PRESSONE™ achieves its intended use through mechanical penetration of the skin and underlying tissue using a sharpened, beveled stainless-steel tip. Fluid transfer occurs via a single internal lumen, utilizing pressure differentials created by attached compatible devices (e.g., syringe).	The BD Hypoint™ achieves its intended use through mechanical penetration of the skin and underlying tissue using a sharpened, beveled stainless-steel tip. Fluid transfer occurs via a single internal lumen, utilizing pressure differentials created by attached compatible devices (e.g., syringe).	Same
Device Components	Stainless Steel cannula attached to a polypropylene hub	Stainless Steel cannula attached to a polypropylene hub	Same
Needle Gauge	25G	25G	Same
Needle Length	5/8”	5/8”	Same
Gauge color	Orange (ISO 6009)	Orange (ISO 6009)	Same
Sterilization Method	Gamma radiation	Gamma radiation	Same
Single-Use	yes	yes	Same
Shelf Life	5 years	5 years	Same
Individual packaging	Hard container with peel off label	Hard container with peel off label	Same
Performance Testing	ISO 9626, ISO 80369-7, ISO 7864	ISO 9626, ISO 80369-7, ISO 7864	Same

Non-Clinical and/or Clinical Tests Summary & 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 performance standards were used.

1) ISO 80369-7:2016, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intervascular or hypodermic applications (General I (QS/RM)
2) ISO 9626:2016, Stainless steel needle tubing for the manufacturer of medical devices (General Plastic Surgery/General Hospital)
3) ISO 7864 Fourth Edition 2016-08-01, Sterile Hypodermic Needles for Single Use - Requirements and Test Methods. (General Plastic Surgery/General Hospital)
4) USP <788> "Particulate Matter in Injections"

Biocompatibility was assessed to ISO 10993-1:2018. Endpoints include Cytotoxicity, Sensitization, Irritation, Systemic Toxicity and Hemocompatibility. All requirements were met.

The packaging, sterility and shelf -life are validated to standards

1) ISO 11137-1:2025 Sterilization of health care products - Radiation. Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices and
2) ASTM D4169, Standard Practice for Performance Testing of Shipping Containers and Systems. All requirements were met.
3) ASTM F1980-16, Standard Guide for Accelerated Aging Of Sterile Barrier Systems For Medical Devices
4) ASTM F1929-15, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
5) ASTM F88/F88M-21, Standard Test Method for Seal Strength of Flexible Barrier Materials

No Clinical testing was performed.

Non-clinical testing results confirm that the subject device complies with applicable voluntary consensus standards pertaining to performance, biocompatibility, packaging, transportation, and sterilization. All testing was successfully conducted in accordance with internal protocols, as well as relevant national and international standards.

Internal verification and validation activities demonstrate that the PRESSONE™ meets its design specifications and exhibits functional performance equivalent to the predicate device. These results support the claim of substantial equivalence to the predicate device in both design and technological characteristics.