April 19, 2023

NP Medical, Inc.
Krishna Govindarajan
Global Quality Regulatory Affairs Manager
101 Union Street
Clinton, Massachusetts 01510

Re: K220288
Trade/Device Name: NP Medical nPulse K150 Neutral Displacement Needle Free Connector, nPulse Neutral displacement needle free connector, nPulse K150 Needle Free Connector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: March 17, 2023
Received: March 20, 2023

Dear Krishna Govindarajan:

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,

David Wolloscheck, Ph.D.
Acting 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)*
K220288

Device Name
NP Medical nPulse™ K150 Neutral Displacement Needle Free Connector

Indications for Use *(Describe)*

The nPulse™ neutral displacement connector is a single patient use, sterile, nonpyrogenic device for needleless access to the IV line and/or IV catheter during IV therapy. The nPulse™ connector can be used for direct injection, intermittent infusion, continuous infusion, or aspiration.

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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K220288 - 510(k) Summary
The following summary is provided in accordance with 21 CFR 807.92

I. SUBMITTER

Owner's Name: NP Medical, Inc.,
Address: 101 Union Street
Clinton, MA 01510
Phone: 978-368-6854

Contact Person: Krishna Govindarajan
email: Krishna_Govindarajan@NPMedical.com

Date Prepared: April 19, 2023

II. DEVICE

Trade/Device Name:	NP Medical nPulse™ K150 Neutral Displacement Needle Free Connector
Common or Usual Name:	Needle Free Connector
Regulation Number:	21 CFR 880.5440
Regulation Name:	Intravascular administration set
Regulatory Class:	Class II
Product Code:	FPA

III. PREDICATE DEVICE (Previously Cleared Device)

NP Medical K100 Neutral Displacement Needle Free Connector (K130023)

IV. DEVICE DESCRIPTION

The nPulse K150 Neutral Displacement Needle Free Connector is a single patient use, sterile, non-pyrogenic device for needleless access to the IV line and/or IV catheter during IV therapy. The nPulse K150 Neutral Displacement Needle Free Connector can be used for direct injection, intermittent infusion, continuous infusion, or aspiration. The nPulse K150 valve is a normally closed, luer-activated, valved connector which has an open mode that permits bi-directional fluid flow and a closed mode that prevents fluid flow.

V. INDICATIONS FOR USE

The nPulse™ neutral displacement connector is a single patient use, sterile, nonpyrogenic device for needleless access to the IV line and/or IV catheter during IV therapy. The nPulse™ connector can be used for direct injection, intermittent infusion, continuous infusion, or aspiration.

K220288 - 510(k) Summary

The following summary is provided in accordance with 21 CFR 807.92

VI.COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed device and predicate device are identical with regards to intended use and are substantially equivalent with regards to design, technological characteristics, performance, safety, and effectiveness. Both devices also have the same indications for use as needle free connector for direct injection, intermittent infusion, continuous infusion or aspiration without the need for sharps devices.

At a high level, the proposed and predicate devices are based on the following same technological element:

- Neutral Displacement Needle Free Connector

The following table provides a comparison of technological characteristics between the subject and predicate device:

Comparison Element	Subject Device – NP Medical nPulse K150	Predicate Device – NP Medical K100 (K130023)	Analysis of Differences
Product Code	FPA	FPA	Same
Regulation Number	880.5440	880.5440	Same
Class	II	II	Same
Intended Use	Intravascular Extension Set	Intravascular Extension Set	Same
Indications for Use	The nPulse™ neutral displacement connector is a single patient use, sterile, nonpyrogenic device for needleless access to the IV line and/or IV catheter during IV therapy. The nPulse™ connector can be used for direct injection, intermittent infusion, continuous infusion, or aspiration.	The K100 Neutral Displacement Connector is a single patient use, sterile, non-pyrogenic device for needleless access to the IV line and/or IV catheter during IV therapy. The K100 connector can be used for direct injection, intermittent infusion, continuous infusion, or aspiration.	Same
Size, shape	26mm L x 12mm D, Cylindrical	26mm L x 12mm D, Cylindrical	Same
Mass	1.55 grams	1.55 grams	Same

K220288 - 510(k) Summary

The following summary is provided in accordance with 21 CFR 807.92

Comparison Element	Subject Device – NP Medical nPulse K150	Predicate Device – NP Medical K100 (K130023)	Analysis of Differences
Components	Inlet, Outlet, Upper Seal, Lower Gland, Post, Slit Lube, G/P Lube	Inlet, Outlet, Upper Seal, Lower Gland, Post, Slit Lube, G/P Lube	Same
Materials	Polycarbonate, LIM Silicone, Silicone Oil	Polycarbonate, LIM Silicone, Silicone Oil	Same. The LIM silicone durometer is adjusted in the subject device.
Displacement Type	Neutral	Neutral	Same
Luer Connector	ISO Luer	ISO Luer	Same
Multiple Activations	200 intermittent	96 intermittent	Different. The subject device has demonstrated applicable performance following 200 activations through Gland Height and Integrity, Back Pressure, and Activated Pressure Resistance.
Indwell	96 hours	96 hours	Same
Use Days	7 days	4 days	Different. The proposed device aligns with current best practices for use days, specifically through an evaluation of the microbial ingress performance over a period of seven days resulting in 0 CFU recovered for all test device replicates, which supports this difference.
Chemical Compatibility	Lipids, Alcohol, Chlorhexidine gluconate (CHG)	Lipids, Alcohol, CHG	Same
Pressure Rating	325 psi	325 psi	Same
Priming Volume	0.12 mL	0.12 mL	Same
Package	Blister	Blister	Same
Sterilization	Ethylene Oxide	Ethylene Oxide	Same

K220288 - 510(k) Summary

The following summary is provided in accordance with 21 CFR 807.92

Comparison Element	Subject Device – NP Medical nPulse K150	Predicate Device – NP Medical K100 (K130023)	Analysis of Differences
Shelf Life	5 years	1 year launch, 3 years planned	Different. The subject device has demonstrated performance after 5 years of aging including microbial ingress testing resulting in 0 CFU recovered for all test device replicates.
Disposable or Reusable	Disposable	Disposable	Same

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

1. **Performance Testing - Bench**

   The functional performance of the proposed device has been evaluated using the appropriate methodology as specified in the FDA recognized consensus standards and in conjunction with NP Medical established test protocols in accordance with the recommendations provided in the FDA guidance document titled "Intravascular Administration Sets Premarket Notification Submissions [510(k)]".

   The following functional performance tests were conducted as part of the Design Verification and Validation activities:

   - Air Bolus and Bubble Free Priming
   - Repeat Insertion
   - Blood Flushing Evaluation
   - Bolus Back Pressure
   - Activated Pressure Resistance
   - Docking Stability
   - Flow Rate
   - Fluid Displacement
   - Gland Height Determination
   - Hydraulic Burst Leak
   - Torque Testing
   - Stress Resistance to Swabbing Chemicals
   - Particulate Contamination, Sub-visible Particles

   In addition, NP Medical has successfully conducted Microbial Ingress testing to support a 7- day change protocol.

K220288 - 510(k) Summary

The following summary is provided in accordance with 21 CFR 807.92

2. Biocompatibility

The biocompatibility evaluation was conducted in accordance with the FDA Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", as recognized by FDA. Biocompatibility of indirect blood path external communicating device (Fluid Pathway) with prolonged contact duration were confirmed by evaluating the following ISO 10993-1 recommended biocompatibility evaluation endpoints.

Fluid Pathway

- Chemical Characterization
- Establishment of Allowable Limits
- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemocompatibility

The proposed device has been found biocompatible for its intended use/indications for use.

3. Sterilization and Shelf Life

The sterilization validation activities have been performed using Ethylene Oxide sterilization method in accordance with ISO 11135:2014 Sterilization of health care products - Ethylene oxide — Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices to state the Sterility Assurance Level (SAL) of 10^{-6} for the proposed device labeled as sterile.

The stability of the package in maintaining sterility has been assessed through the transit and storage life cycles in accordance with the ISO 11607-1:2019 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems by way of visual assessment, package peel strength and sterile package integrity (bubble test) following applicable conditioning.

VIII. CLINICAL DATA

Not applicable.

IX. CONCLUSIONS

NP Medical believes that the NP Medical nPulse™ K150 Neutral Displacement Needle Free Connector as indicated in this traditional 510(k) premarket notification submission is substantially equivalent to the predicate device NP Medical K100 Neutral Displacement Needle Free Connector (K130023).