November 3, 2022

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

Re: K221518
Trade/Device Name: NP Medical nCompass Extension Set with Stabilizing Base
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: October 4, 2022
Received: October 5, 2022

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.
For Payal Patel
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)*
K221518

Device Name
NP Medical nCompass Extension Set with Stabilizing Base

Indications for Use *(Describe)*
The NP Medical Extension Set with stabilizing base is a sterile single patient use device.

The NP Medical Extension Set is intended for direct injection, intermittent infusion, continuous infusion or aspiration for all patients for which IV therapy is prescribed.

The NP Medical Extension Set incorporates a normally closed bidirectional pressure-activated valve that prevents low pressure retrograde flow and is intended for power injector procedures to a maximum pressure of 325 psi at a flow rate of 10ml per second.

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

The following summary is provided in accordance with 21 CFR 807.92:

I. SUBMITTER

NP Medical, Inc.,
101 Union Street
Clinton, MA 01510
Phone: 978-368-6854

Contact Person: Krishna Govindarajan
Date Prepared: November 3, 2022

II. DEVICE

Trade/Device Name: NP Medical nCompass™ Extension Set with Stabilizing Base
Common or Usual Name: Extension Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA

III. PREDICATE DEVICE

Primary Predicate Device:
Velano Vascular Velano ExT™ Extension Set (K200439).

Reference Device:
Nexus Medical, Nexus TKO®-6P, Luer Activated Device (K130416).

IV. DEVICE DESCRIPTION

The NP Medical Extension Set with Stabilizing Base is a sterile, single use, nonpyrogenic intravenous administration extension set comprised of a side-to-side repositionable tube bonded to a connector hub on one end and a female luer on the other end with a clamp in between. The connector hub has a locking male luer and a rotating tube connection joint. The hub houses a bidirectional Pressure-Activated Valve (PAV) and an integral stabilizer under the connector hub. The stabilizing base component (along with IV tape / adhesive) is intended to help anchor the extension set to the patient. This device is not made with plasticizers Diethylhexylphthalate (DEHP). The NP Medical Extension Set with Stabilizing Base may be used with compatible Vascular Access Devices (VAD), Needle Free Connectors, and other commercially available devices.

510(k)Summary

The following summary is provided in accordance with 21 CFR 807.92:

V. INDICATIONS FOR USE

The NP Medical Extension Set with stabilizing base is a sterile single patient use device.

The NP Medical Extension Set is intended for direct injection, intermittent infusion, continuous infusion or aspiration for all patients for which IV therapy is prescribed.

The NP Medical Extension Set incorporates a normally closed bidirectional pressure-activated valve that prevents low pressure retrograde flow and is intended for power injector procedures to a maximum pressure of 325 psi at a flow rate of 10ml per second.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Primary Predicate Device:
The proposed device and primary 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 extension set for direct injection, intermittent infusion, continuous infusion, or aspiration for which IV therapy is prescribed.

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

- Intravascular administration set/extension set

The following technological differences exist between the subject and predicate devices:

- Use of rotating tube connection joint for repositionable extension tube
- Use of integrated Pressure Activated Valve (PAV) for retrograde flow control

Reference Device:
The proposed device integrated Pressure Activated Valve (PAV) for retrograde flow control functionality and reference device bidirectional pressure activated valve functionality are identical with regards to operating principle, technological characteristics, performance, safety, and effectiveness. Both the proposed device and reference device include a normally closed bidirectional pressure activated valve that opens in the forward direction enabling infusion, and in the reverse direction enabling blood aspiration.

510(k)Summary

The following summary is provided in accordance with 21 CFR 807.92:

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

Comparison Element	Subject Device – NP Medical Extension Set with stabilizing base	Predicate Device – Velano ExT™ Extension Set (K200439)	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 NP Medical Extension Set with stabilizing base is a sterile single patient use device. The NP Medical Extension Set is intended for direct injection, intermittent infusion, continuous infusion or aspiration for all patients for which IV therapy is prescribed. The NP Medical Extension Set incorporates a normally closed bidirectional pressure-activated valve that prevents low pressure retrograde flow and is intended for power injector procedures to a maximum pressure of 325 psi at a flow rate of 10ml per second.	The Velano ExT™ Extension Set with needle free connector is for single use only. Each port of the Velano ExT™ Extension Set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. The pressure rated port of the Velano ExT™ Extension Set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10ml per second.	Different. The subject device does not reference elements associated with the needle free connector of the predicate device. These excluded features are intended for Velano's PIVO™ compatibility for which the subject device does not seek to claim. Added the incorporation of a normally closed bidirectional pressure-activated valve similar to reference device K130416. (Performance tests leveraged from the reference device: Retrograde pressure resistance and PAV robustness) Device Flow Rate (gravity and pressurized) and Dynamic Hemolysis (per USP <788>) testing performed to demonstrate substantial equivalence.

510(k)Summary

The following summary is provided in accordance with 21 CFR 807.92:

Comparison Element	Subject Device – NP Medical Extension Set with stabilizing base	Predicate Device – Velano ExT™ Extension Set (K200439)	Analysis of Differences
Extension Set Components /Materials	Male Luer cap/HDPE Male Luer/PC Male Luer spin lock connector/PC Tubing/PVC Pinch clamp/POM Female Luer/PC Female Luer Cap/HDPE Fluid Path Body/Si, PC Stabilizer/ Polystyrene, Acrylic PSA, Polycoated LDPE Pressure activated valve/Si	Male Luer cap/HDPE Male Luer/PC Male Luer spin lock connector/PC Tubing/PVC Pinch clamp/POM Female Luer/PC Female Luer Cap/HDPE Fluid Path Body/Si, PC Stabilizer/ Polystyrene, Acrylic PSA, Polycoated LDPE Pressure activated valve/Si	Different. The subject stabilizer uses a polystyrene fabric with acrylic PSA and Polycoated LDPE liner instead of TPE on the predicate. There is no T-Port connector on subject device since PIVO™ compatibility is not required. The subject device adds a PAV. ISO 10993 biocompatibility testing was conducted to demonstrate these changes did not affect the product performance and did not raise any questions of safety or effectiveness.
Overall Length	Overall Length: 3.7 inches (9.3cm)	Overall Length: 5.0 inches (12.7cm)	Different. The subject device has a shorter overall length. Priming Volume, Device Flow Rate (gravity and pressurized) and Dynamic Hemolysis (per USP <788>) testing conducted did not raise any questions of safety or effectiveness.
Priming Volume	< 1 mL	< 1 mL	Same
Particulate	USP 788	USP 788	Same
Device flow rate (gravity)	Equal to or greater than 3 L/hr.	Equal to or greater than 3 L/hr	Same
Device flow rate (pressurized)	Equal to or greater than 10ml/second from the device distal end at a pressure at or below 325psi.	Use with low pressure power injectors up to 325psi and maximum flow rate of 10mL/sec	Same
Energy Source	User Operated	User Operated	Same
Sterilization Method & Minimum SAL	Ethylene Oxide Minimum SAL $1X10^{-6}$	Ethylene Oxide Minimum SAL $1X10^{-6}$	Same

510(k)Summary

The following summary is provided in accordance with 21 CFR 807.92:

Comparison Element	Subject Device – NP Medical Extension Set with stabilizing base	Predicate Device – Velano ExT™ Extension Set (K200439)	Analysis of Differences
Packaging	Reinforced paper / formed blister (PP/LDPE)	Reinforced paper / formed blister (nylon)	Different. The subject uses a Tyvek + PP/LDPE package that meets ISO 11135 and ISO 11607-1 requirements.
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:

- Device flowrate (gravity and pressurized)
- Retrograde pressure resistance
- Dynamic hemolysis
- Positive pressure
- 325psi burst resistance (for rotating tube connection and other joints)
- Extension tube bond integrity
- Stabilization pad bond integrity
- Extension tubing port (rotating connection) interfaces, sub-atm. pressure air leakage
- Resistance to overriding
- ESC resistance to lipids
- PAV robustness
- Particulate contamination, sub-visible particles

The results of the functional performance testing demonstrated that the proposed device met all requirements and the differences in design, such as rotating tube connection joint and integrated bidirectional Pressure-Activated Valve (PAV) feature do not affect the final product performance and the safety or effectiveness of the proposed device.

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.

510(k)Summary

The following summary is provided in accordance with 21 CFR 807.92:

Biocompatibility of intact skin surface device (Stabilizing Base) and 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.

Stabilizing Base

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity

Extension Set Fluid Pathway

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

All the Biocompatibility study results satisfy the acceptance criteria specified by the above applicable standards and 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.

VIII. CLINICAL DATA

Not applicable.

IX. CONCLUSIONS

NP Medical believes that the NP Medical Extension Set with Stabilizing Base is to be as safe, as effective, and substantially equivalent in performance to the above identified predicate device.