December 4, 2025

NP Medical
Albert Sanford
Director, Quality Assurance & Regulatory Affairs
101 Union Street
Clinton, Massachusetts 01510

Re: K251257
Trade/Device Name: nSet+ Stabilization Set [6426733]; nSet+ Stabilization Set with nSyte Needle Free Connector (NFC) [6426731]; nSyte Needle Free Connector (NFC) [6426727]
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: November 3, 2025
Received: November 3, 2025

Dear Albert Sanford:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

DAVID WOLLOSCHECK -S

David Wolloscheck, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251257

Device Name
nSet+ Stabilization Set [6426733]
nSet+ Stabilization Set with nSyte Needle Free Connector (NFC) [6426731]
nSyte Needle Free Connector (NFC) [6426727]

Indications for Use *(Describe)*

Product Name: nSet+ Stabilization Set
Part Number: 6426733
The nSet+ Stabilization Set is for single use only. The nSet+ Extension Set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. The nSet+ Extension Set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10 ml per second.

Product Name: nSet+ Stabilization Set with nSyte Needle Free Connector (NFC)
Part Number: 6426731
The nSet+ Stabilization Set with nSyte needle free connector is for single use only. The nSet+ Extension Set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. The nSet+ Stabilization Set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10 ml per second.

Product Name: nSyte Needle Free Connector (NFC)
Part Number: 6426727
The nSyte needle free connector is for single use only. The nSyte needle free connector may be used for direct injection, intermittent infusion, continuous infusion or aspiration. The nSyte needle free connector may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10 ml 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) #: K251257

510(k) Summary

Prepared on: 2025-12-02

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	NP Medical
Applicant Address	101 Union Street Clinton MA 01510 United States
Applicant Contact Telephone	508.838.1564
Applicant Contact	Mr. Albert Sanford
Applicant Contact Email	Bert.Sanford@npmedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	nSet+ Stabilization Set [6426733] nSet+ Stabilization Set with nSyte Needle Free Connector (NFC) [6426731] nSyte Needle Free Connector (NFC) [6426727]
Common Name	Intravascular administration set
Classification Name	Set, Administration, Intravascular
Regulation Number	880.5440
Product Code(s)	FPA

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K200439	Velano ExT Extension Set	FPA

Device Description Summary

21 CFR 807.92(a)(4)

Product Name: nSet+ Stabilization Set
Part Number: 6426733
Description: The nSet+ Stabilizing Set is a sterile, single patient use, add-on medical device used in peripheral vascular access systems. The nSet+ Stabilizing Set includes a stabilization base, an extension tube, a tube pinch clamp, and terminates with locking ISO 80369-7 connectors on each end, capped.
It is sold individually blister packed with fifty (50) total units per carton and is labeled with a shelf life of one year.

Product Name: nSet+ Stabilization Set with nSyte Needle Free Connector (NFC)
Part Number: 6426731
Description: The nSet+ Stabilizing Set with nSyte Needle Free Connector is a sterile, single patient use, add-on medical device used in peripheral vascular access systems.
The nSet+ Stabilizing Set includes a stabilization base, an extension tube, a tube pinch clamp, an nSyte Needle Free Connector, and terminates with a locking ISO 80369-7 male connector, capped.
It is sold individually blister packed with fifty (50) total units per carton and is labeled with a shelf life of one year.

Product Name: nSyte Needle Free Connector (NFC)
Part Number: 6426727
Description: The nSyte Needle Free Connector is a sterile, single patient use, add-on medical device used in peripheral vascular access systems.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Product Name: nSet+ Stabilization Set
Part Number: 6426733
The nSet+ Stabilization Set is for single use only. The nSet+ Extension Set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. The nSet+ Extension Set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10 ml per second.

Product Name: nSet+ Stabilization Set with nSyte Needle Free Connector (NFC)
Part Number: 6426731
The nSet+ Stabilization Set with nSyte needle free connector is for single use only. The nSet+ Extension Set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. The nSet+ Stabilization Set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10 ml per second.

Product Name: nSyte Needle Free Connector (NFC)
Part Number: 6426727
The nSyte needle free connector is for single use only. The nSyte needle free connector may be used for direct injection, intermittent infusion, continuous infusion or aspiration. The nSyte needle free connector may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10 ml per second.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The nSet+ and predicate device have the same indications for use.

Technological Comparison

21 CFR 807.92(a)(6)

The proposed devices are substantially equivalent to the predicate device previously cleared under K200439 on February 23, 2021. The proposed devices have the same indications for use as an extension set for direct injection, intermittent infusion, continuous infusion, or aspiration for which IV therapy is prescribed. The proposed devices and the predicate differ slightly in design and technological characteristics as follows:

- The nSyte Needle Free Connector (NFC) [6426727] comprises only the needle-free connector elements of the predicate device, utilizing identical materials and Luer connectors.
- The nSet+ Stabilization Set [6426733] is identical to the predicate device in all features including materials of construction, tubing length, and Luer connectors, but does not include the needle-free connector portion of the predicate device.
- The nSet+ Stabilization Set with nSyte Needle Free Connector (NFC) [6426731] differs from the predicate device only in where the needle-free connector portion is positioned along the tubing; the materials of construction and device configuration (i.e. tubing length, Luer connections) are identical to the predicate device.

These differences do not affect the final product performance nor raise any questions of safety or effectiveness as demonstrated by the bench testing.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Performance Testing - Bench

The following nonclinical performance testing supports the proposed devices:

- Priming volume
- Microbial ingress
- Particulate contamination, sub-visible particles
- 325psi burst resistance
- Flow rate for normal use and power injection
- Spin collar height and spin collar angle
- Tubing bond strength
- ESC resistance to lipids
- Multiple engagement
- Continuous engagement
- Tubing kink resistance

Biocompatibility Testing

The biocompatibility evaluation was conducted in accordance with 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 with prolonged contact duration was confirmed by evaluating the following ISO 10993-1 recommended biocompatibility evaluation endpoints.

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

The proposed devices have been found biocompatible for the intended use/indications for use.

Clinical Tests "Not Applicable".

Conclusions:
The testing conducted by NP Medical demonstrates that the design outputs of nSet+ Product Family meet the design inputs. The performance and other characteristics were as expected when compared to the acceptance criteria established in the governing protocols. Additionally, the user needs were validated, as the associated test results satisfied the validation acceptance criteria.
The results of the testing are consistent with the performance of the predicate device and support NP Medical's assessment of the nSet+ Product Family's substantial equivalence to the predicate device.