



March 15, 2024

Poly Medisure Limited
% Sunita Teekasingh
Regulatory Consultant
GSA 2 Group LLC
8049 Hayes Street North East
Spring Lake Park, Minnesota 55432

Re: K232234

Trade/Device Name: Nouvo Safety Set
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: February 15, 2024
Received: February 16, 2024

Dear Sunita Teekasingh:

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.

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,



Porsche Bennett
For 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

Indications for Use

510(k) Number (if known)

K232234

Device Name

Nouvo Safety Set

Indications for Use (Describe)

The Nouvo Safety Set IV Catheter are indicated for insertion into a patient's vascular system to sample blood, Infusion of fluids such as solutions, parenteral nutrition and administration of other drugs. The catheters may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. The 18G-22G catheters may be used intravascularly with power injectors at a maximum pressure of 300 psi.

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.

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**K232234- 510(k) Summary
Complies with 21CFR 807.92**

I. SUBMITTER

Poly Medicure Limited
Plot No. 115-117, Sector- 59
HSIIDC Industrial Area, Ballabgarh
Faridabad-121004, Haryana
INDIA

Contact Person: Sunita Teekasingh, RN, BSN, CCRN
Consultant, GSA2 Group LLC
Phone: 612-814-7999
Email: gsa2groupllc@gmail.com

Date Prepared: March 15, 2024

II. DEVICE

Name of Device:	Nouvo Safety Set
Common Name or Usual Name:	Intravascular Catheter
Classification Name:	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days 21 (CFR §880.5200)
Regulatory Class:	II
Primary Product Code	FOZ

III. PREDICATE DEVICE

510(k) Number:	K183399
Name of Device:	BD Nexiva™ Closed IV Catheter System
Common Name or Usual Name:	Intravascular Catheter
Classification Name:	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days 21 (CFR §880.5200)
Regulatory Class:	II
Primary Product Code	FOZ

There are no reference devices used in this submission.

IV. DEVICE DESCRIPTION

The Nouvo Safety Set is an over the Needle Intravascular Catheter, peripheral, it incorporates the passive safety clip to help prevent needle stick injuries. The catheter is made from a radio-opaque polyurethane (PUR) material. The devices have a septum, stabilization platform, integrated extension tubing, c-clamp, single luer, needle free connector, safety clip, access split septum with site luer and vent plug. The needle cover protects the needle and catheter.

The color of the catheter hub identifies the gauge size, the catheter gauge size and length are identified on the product packaging. The Nouvo safety set IV catheter is provided sterile and non-pyrogenic for single use only. The Nouvo safety set IV catheter is not made with natural rubber latex or PVC.

The subject device shares the similar technological characteristics, principles of operation and the same fundamental scientific technology as the predicate device. Both devices have needleless adaptors and passive safety features. The Needleless adaptor used in the subject device is FDA cleared.

The Nouvo Safety Set has the following features: needle cover, introducer needle, needle hub, radiopaque catheter, colored wings, catheter hub, C-clamp, extension tube with or without the N-Pulses needles connection (single port, single port with needle free valve, dual port, dual port with needle free valve) cleared under K220288 (NP Medical). The immediate flashback system has a plug that prevents leaking and seepage. Upon removal, the safety clip is engaged to prevent needle sticks.

There are no additional accessories included with the Nouvo Safety Set.

The subject device has the following models/configurations:

Gauge	Safety I.V Cannula	Extension Tube	Wing	PUR-Catheter	Y-site,	C-Clamp	SQ FB chamber with filter	N-Pulse ¹	Tyvek Pack
18Gx45mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
18Gx32mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
18Gx64mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
20Gx64mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
20Gx45mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
20Gx32mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
20Gx25mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
22Gx64mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
22Gx45mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
22Gx25mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
22Gx19mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
24Gx19mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
24Gx14mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
26Gx19mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	, Yes
18Gx45mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2- Yes	Yes
18Gx32mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2- Yes	Yes
18Gx64mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2- Yes	Yes
20Gx64mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2- Yes	Yes
20Gx45mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2- Yes	Yes
20Gx32mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2- Yes	Yes
20Gx25mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2- Yes	Yes
22Gx64mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2- Yes	Yes
22Gx45mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2- Yes	Yes
22Gx25mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2- Yes	Yes
22Gx19mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2- Yes	Yes
24Gx19mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2- Yes	Yes
24Gx14mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2- Yes	Yes
26Gx19mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2- Yes	Yes
18Gx45mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
18Gx64mm	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
18Gx32mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
20Gx64mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
20Gx45mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
20Gx32mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
20Gx25mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
22Gx64mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
22Gx45mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
22Gx25mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
22Gx19mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
24Gx19mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

¹N-Pulse is a subcomponent cleared under K220288

Gauge	Safety I.V Cannula	Extension Tube	Wing	PUR-Catheter	Y-site,	C-Clamp	SQ FB chamber with filter	N-Pulse ¹	Tyvek Pack
24Gx14mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
26Gx19mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
18Gx45mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2-Yes	Yes
18Gx32mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2-Yes	Yes
18Gx64mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2-Yes	Yes
20Gx64mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2-Yes	Yes
20Gx45mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2-Yes	Yes
20Gx32mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2-Yes	Yes
20Gx25mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2-Yes	Yes
22Gx64mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2-Yes	Yes
22Gx45mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2-Yes	Yes
22Gx25mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2-Yes	Yes
22Gx19mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2-Yes	Yes
24Gx19mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2-Yes	Yes
24Gx14mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2-Yes	Yes
26Gx19mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2-Yes	Yes,
18Gx45mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
18Gx32mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
20Gx64mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
20Gx45mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
20Gx32mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
20Gx25mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
22Gx64mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
22Gx45mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
22Gx25mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
22Gx19mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
24Gx19mm	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
24Gx14mm	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
26Gx19mm	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
18Gx45mm	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
18Gx32mm	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes,
18Gx64mm	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes,
20Gx64mm	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
20Gx45mm	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
20Gx32mm	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
20Gx25mm	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
22Gx64mm	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
22Gx45mm	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
22Gx25mm	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
22Gx19mm	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
24Gx19mm	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
24Gx14mm	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
26Gx19mm	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
18Gx45mm	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes
18Gx64mm	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes
18Gx32mm	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes
20Gx64mm	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes
20Gx45mm	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes
20Gx32mm	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes
20Gx25mm	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes
22Gx64mm	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes
22Gx45mm	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes
22Gx25mm	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes
22Gx19mm	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes
24Gx19mm	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes
24Gx14mm	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes
26Gx19mm	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes

V. INDICATIONS FOR USE

The Nouvo Safety Set IV Catheter are indicated for insertion into a patient's vascular system to sample blood, Infusion of fluids such as solutions, parenteral nutrition and administration of other drugs. The

catheters may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. The 18G-22G catheters may be used intravascularly with power injectors at a maximum pressure of 300 psi.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1: Subject and Predicate Device Comparison

FEATURE	SUBJECT DEVICE Nouvo Safety Set	PREDICATE DEVICE BD Nexiva™ Closed IV Catheter System	COMPARISON
Device Manufacturer	Poly Medisure Limited	Becton Dickson	N/A
510(k) Reference	K232234	K183399	N/A
Indications For Use	The Nouvo Safety Set IV Catheter are indicated for insertion into a patient's vascular system to sample blood, Infusion of fluids such as solutions, parenteral nutrition, and administration of other drugs. The catheters may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. The 18G-22G catheters may be used intravascularly with power injectors at a maximum pressure of 300 psi.	BD Nexiva closed IV catheter systems are intended to be inserted into a patient's peripheral vascular system for short term use to sample blood, monitor blood pressure, or administer fluids. These devices may be used for any patient population with consideration given to adequacy of vascular anatomy, procedure being performed, fluids being infused, and duration of therapy. The 22- 18 GA (0.9-1.3 mm) devices are suitable for use with power injectors set to a maximum pressure of 300 psi (2068 kPa) when access ports not suitable for use with power injectors are removed.	Similar, Refer to comment a
Models	Extension tube- with and without access port	Extension tube with and without access port	Same
Product configurations	• Single port, • Dual port, • Single port with needle free valve, • Dual port with needle free valve	• Single Port, • Single Port with MaxZero, • Dual Port, • Dual Port with Q-Syte, • Dual Port with Q-Syte and End Cap, • Dual Port with MaxZero	Similar, Refer to comment b

FEATURE	SUBJECT DEVICE Nouvo Safety Set	PREDICATE DEVICE BD Nexiva™ Closed IV Catheter System	COMPARISION
Fundamental Scientific Technology	Closed peripheral intravascular catheter system designed with an integrated extension set incorporating a single port or Y (dual)-port injection site. Incorporates flashback visualization.	Closed peripheral intravascular catheter system designed with an integrated extension set incorporating a single port or Y (dual)-port injection site. Incorporates BD Instaflash™ technology to assist with flashback visualization.	Same
Sharps Injury Protection Feature	Yes- passive	Yes - passive	Same
X-Ray Visible	Yes	Yes	Same
Needle Material	Stainless steel	Stainless steel	Same
Needle Distal End Configuration	Back cut ground beveled needle	Back cut ground beveled needle	Same
Flashback Visualization	Yes	Yes	Same
Catheter Tube Material	Polyurethane + Barium Sulfate	Polyurethane + Barium Sulfate	Same
Catheter Adapter Wings	TPE + Gauge-specific colorant	TPE + Gauge-Specific Colorant	Same
Catheter Adapter	Cellulose Acetate Propionate / Polycarbonate / Acrylonitrile Butadiene Styrene	Copolyester	Different, Refer to comment c
Tip Shield	Polycarbonate	Polycarbonate + Grey Colorant	Similar, Refer to comment d
Grip/Needle Hub	Acrylonitrile Butadiene Styrene (exel white)	Polycarbonate + White Colorant	Different, Refer to comment e
Pinch Clamp	Polyacetal	Polyacetal	Same
Extension Tubing	Polyurethane	Polyurethane	Same
Luer Adapter	Acrylonitrile Butadiene Styrene	Copolyester	Different, refer to comment f
Needleless Adapter	Yes (FDA cleared K220288)	Yes- MaxZero	Similar, refer to comment g
Blood control	Yes	Yes	Same
Gauge sizes	18 - 26G	18- 24G	Same
Catheter Lengths (inch)	0.55 IN, 0.75 IN, 1.00 IN, 1.25 IN, 1.77 IN, 2.52 IN	0.56 IN, 0.75 IN, 1.00 IN, 1.25 IN, 1.75 IN	Similar, refer to comment h
Color-Coding	Yes, according to ISO. 10555-5	Yes, according to ISO. 10555-5	Same
Proximal End Configuration	Female 6 % Luer	Female 6 % Luer	Same
Single Use	Yes	Yes	Same
Sterile	Yes, SAL 10-6	Yes, SAL 10-6	Same

FEATURE	SUBJECT DEVICE Nouvo Safety Set	PREDICATE DEVICE BD Nexiva™ Closed IV Catheter System	COMPARISION
Sterilization Method	Ethylene oxide	Ethylene oxide	Same
Shelf Life	5 years	3 years	Different, refer to comment i
Physical Properties	According to ISO 10555-1, ISO 10555-5	According to ISO 10555-1, ISO 10555-5	Same
Power Injection Usage?	Yes, 18-22 G catheters up to 300 psi.	The 18-22 G devices are suitable for use with power injectors up to 300 psi	Same
Biocompatibility	Biocompatible in accordance with ISO 10993 series and FDA guidance	Biocompatible in accordance with ISO 10993 series	Same
Prescription or Rx Only	Rx only	Rx only	Same
MRI Safety	MR Conditional	Unknown	Different, refer to comment j

The following section describes the differences between the subject and the predicate device:

a. Indications for Use

The predicate and the subject devices have minor differences between the statements within the IFU. The differences do not raise different questions of safety and effectiveness.

b. Product Configurations

The subject and predicate device have different product configurations. Biocompatibility, sterility, performance, shipping, and shelf-life testing of the subject device demonstrates that the differences do not raise different questions of safety and effectiveness.

c. Catheter Adapter

The catheter adapter of the subject device is made of Cellulose Acetate Propionate / Polycarbonate / Acrylonitrile Butadiene Styrene while the catheter adapter provided in the predicate device is made of Copolyester. The safety and performance of catheter adapter has been proven with stability study and biocompatibility of the subject device. The differences do not raise different questions of safety and effectiveness.

d. Tip Sheild

The tip shield of the subject and predicate device is of the same material; however, the predicate device has a colorant. The subject device biocompatibility testing demonstrates the difference does not raise different questions of safety and effectiveness.

e. Grip/Needle Hub

The Grip/needle hub of the subject device is made of Acrylonitrile Butadiene Styrene (exel white) while the Grip/needle hub provided in the predicate device is made of Polycarbonate + white colorant. The safety

and performance of Grip/needle hub has been proven with stability study and biocompatibility of the subject device. The differences do not raise different questions of safety and effectiveness.

f. Luer Adapter.

The Luer adapter of the subject device is made of ABS while the Luer adapter provided in predicate device is made of Copolyester. The safety and performance of luer adapter has been proven with stability study and biocompatibility of subject device. The differences do not raise different questions of safety and effectiveness.

g. Needleless Adapter

Both devices have a needleless system with similar technology. The needleless adaptor used in subject device is FDA cleared (K220288), additional validation was conducted with the Nouvo Safety Set. The differences do not raise different questions of safety and effectiveness.

h. Catheter Lengths

The subject device is available in a long length and has been evaluated for the same safety and performance requirements and performs the same as the predicate shorter lengths. The differences do not raise different questions of safety and effectiveness.

i. Shelf Life

The subject device has a shelf of 5 years while the predicate device has a shelf life of 3 years. Shelf life for the subject devices has been assessed by means of subjecting devices to accelerated aging in accordance with ASTM F1980 (FDA recognition # 14-497) and then by testing them to confirm compliance with specifications at the end of their designated shelf lives. These tests have resulted in the establishment of a shelf life of 5 years. The differences do not raise different questions of safety and effectiveness.

j. MR Safety

The subject device is MR conditional and related information provided in IFU. However, predicate device is unknown with respect to MR safety. The predicate device is not labelled with respect to its compatibility with magnetic resonance (MR) systems. The differences do not raise different questions of safety and effectiveness.

VII. PERFORMANCE DATA

Bench testing has been successfully conducted to ensure the safety and effectiveness of the Nouvo Safety Set, to verify conformity to specification, and demonstrate substantial equivalence to the predicate device cited in this submission.

Testing has included a demonstration of compliance testing with the following standards:

Table 2: FDA Recognized Standards

Standard	FDA Recognition Number
ISO 10555-1:2013/AMD 1:2017	FDA recognition # 6-408
ISO 10555-5:2013	FDA recognition # 6-303
ISO 80369-7:2021	FDA recognition # 5-115
USP <788> Method 1	not FDA recognized

The Nouvo Safety Sets have been subjected to testing in accordance with FDA ‘Guide for Industry and staff – Medical Devices with Sharp injury Prevention Features’ and ISO 23908:2011 ‘Sharps injury protection. Requirements and Test method. Sharp protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.

a. Biocompatibility

Biocompatibility of components in direct or indirect contact with the patient has been established by testing in accordance with the matrix included in Annex A of ISO 10993-1:2018, while taking into consideration relevant FDA guidance’s and, including the following tests:

Table 3: Biocompatibility Recognized Standards

Tests	FDA Recognition number
Cytotoxicity	ISO 10993-5:2009, FDA recognition # 2-245
Sensitization	ISO 10993-10:2010, FDA recognition # 2-174
Irritation or intracutaneous reactivity	ISO 10993-10:2010, FDA recognition # 2-174
Acute systemic toxicity	ISO 10993-11:2017, FDA recognition # 2-255
Subacute/sub chronic toxicity	ISO 10993-11:2017, FDA recognition # 2-255
Material-mediated pyrogenicity	ISO 10993-11:2017, FDA recognition # 2-255
Hemocompatibility	ISO 10993-4:2017, FDA recognition # 2-248
Implantation	ISO 10993-6:2016, FDA recognition # 2-247
Genotoxicity	ISO 10993-3:2014, FDA recognition # 2-228

All tests were successfully completed.

b. Packaging

Sterile packaging is performed at Polymed in accordance with internal documentation (drawings and work instructions).

The sterile packaging materials use Tyvek / MG Paper supplied by Amcor or Qingdao Medlight Trade Co Ltd or Anhui Harmony Medical + PVC Film supplied by Rainbow Industries / Soft blister film.

c. Shipping Packaging

The subject devices are packed for transport in 5 ply corrugated boxes. A transit test has been successfully conducted in accordance with ISTA 3A:2018 (FDA recognition # 5-126).

d. Sterilization

Sterilization is conducted on-site by Polymed by means of ethylene oxide (ETO) gas, resulting in a sterility assurance level (SAL) of 10^{-6} . The cycle has been validated in accordance with ISO 11135:2014/Amd 1:2018 (FDA recognition # 14-529).

ETO residuals have been assessed in accordance with ISO 10993-7:2008/Amd 1:2019 and found to be within acceptable limits.

Bacterial endotoxin levels of ‘ready for release’ devices have been assessed by means of a Limulus amoebocyte lysate (LAL) test in accordance with USP <85> (FDA recognition # 14-561) and found to be less than the allowable limit of ≤ 20 EU/device.

e. Shelf Life

The shelf life for the subject devices has been assessed by subjecting them to accelerated aging per ASTM F1980-16 (FDA recognition #14-497) and then by evaluating them to confirm compliance with specifications at the end of their designated shelf lives. These tests have resulted in the establishment of a shelf life of 5 years.

f. Final Testing and Batch Release

Final testing is performed on each batch before release, testing samples for compliance with:

Table 4 Batch testing FDA Recognized Standards

Standard	FDA Recognition number
ISO 10555-1:2013/AMD 1:2017	FDA recognition # 6-408
ISO 10555-5:2013	FDA recognition # 6-303
ISO 80369-7:2021	FDA recognition # 5-115
USP <788> Method 1	Not FDA recognized

g. Risk Analysis

This submission includes the risk analysis, including human factors. The analysis was performed taking into consideration the requirements of ISO 14971:2019 to demonstrate that all reasonably foreseeable risks have been identified and, where necessary, mitigated, such that the benefits of use outweigh any residual risks of use.

h. Labeling

Labeling has been developed considering FDA requirements and guidance, relevant international standards, predicate device labeling, and usability testing results.

i. Clinical Testing:

Not Applicable

VIII. CONCLUSIONS

The subject and predicate devices have similar indications for use and fundamental technological characteristics. Any differences in technological characteristics between subject and predicate devices are addressed. All variations between the predicate device and subject devices have been tested for device safety and performance. These differences do not raise different questions of safety and effectiveness. The performance data demonstrates that the subject device is substantially equivalent to the predicate device.