November 12, 2024

phenox Ltd
Rachel McDaid
Senior Regulatory Affairs Specialist
Kamrick Court
Ballybrit Business Park
Galway H91 XY38
Ireland

Re: K242420
Trade/Device Name: pNOVUS 21 Microcatheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO, QJP
Dated: August 15, 2024
Received: August 15, 2024

Dear Rachel McDaid:

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,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
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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)*
K242420

Device Name
pNOVUS 21 Microcatheter

Indications for Use *(Describe)*
The pNOVUS 21 Microcatheter is indicated for use with compatible accessories, such as guidewires and guide catheters, in the delivery of interventional devices and infusion of diagnostic agents, such as contrast media, into the neuro vasculature during diagnostic and/or therapeutic procedures. It is not intended for use in peripheral or coronary vasculature.

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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pNOVUS 21 Microcatheter Traditional 510(k)

K242420 510(k) Summary (21 CFR 807.92)

I. SUBMITTER

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Galway, Ireland H91 XY38

Contact Person: Rachel McDaid
Phone: +353 (0)91 740128
Date Prepared: October 29, 2024

II. DEVICE

Device Tradename: pNOVUS 21 Microcatheter
Common or Usual Name: Diagnostic intravascular catheter
Classification: Class II device according to 21 CFR 870.1200 (diagnostic intravascular catheter), 21 CFR 870.1250 (catheter, percutaneous, neurovasculature)
Product Code and Review Panel:

Product Code	DQO	QJP
Primary/Secondary Code	Primary	Secondary
Review Panel	Cardiovascular	Neurology

III. PREDICATE DEVICE

Name of Predicate Device: pNOVUS 21 Microcatheter
Name of Predicate Device Manufacturer: phenox Ltd
510(k) number of Predicate Device: K221279

IV. DEVICE DESCRIPTION

Device Description:

The pNOVUS 21 Microcatheter (pNOVUS 21) is a single use microcatheter, supplied sterile using ethylene oxide (EtO), in a packing hoop, within a sealed pouch and shelf carton configuration. An introducer sheath and shaping mandrel are supplied on a backing card inside the pouch. The packaging is designed to facilitate ease of handling and aseptic presentation of the device.

The pNOVUS 21 Microcatheter is a variable stiffness single lumen catheter. The pNOVUS 21 has a radiopaque marker on the distal end to facilitate fluoroscopic visualization, and a luer hub on the proximal end to facilitate the infusion of diagnostic agents and the smooth transfer of other devices (e.g., guidewires) into the inner lumen of the microcatheter. The distal end of the microcatheter's external surface has a hydrophilic coating applied for increased lubricity during use. The pNOVUS 21 has a straight tip. Steam shaping of the distal tip allows for one-time customizing of the tip shape. There are two models of the pNOVUS 21 Microcatheter, the device model # are:
- PNOV-21-160
- PNOV-21-150

The pNOVUS 21 Microcatheter is intended for use with compatible accessories, such as guidewires and guide catheters, in the delivery of interventional devices and infusion of diagnostic agents, such as contrast media, into the neuro vasculature during diagnostic and/or therapeutic procedures. pNOVUS 21 is generally inserted either through a sheath or guide-catheter.

Environment of Use:

The pNOVUS 21 is solely intended for use by trained physicians in a healthcare facility/hospital.

V. INDICATIONS FOR USE

Table 1: Comparison of Indications for Use of the pNOVUS 21 Microcatheter and predicate device pNOVUS 21 Microcatheter

Parameter	Predicate Device K221279	Subject Device K242420
Indications for Use	The pNOVUS 21 Microcatheter is indicated for use with compatible accessories, such as guidewires and guide catheters, in the delivery of interventional devices and infusion of diagnostic agents, such as contrast media, into the neuro vasculature during diagnostic and/or therapeutic procedures. It is not intended for use in peripheral or coronary vasculature.	The pNOVUS 21 Microcatheter is indicated for use with compatible accessories, such as guidewires and guide catheters, in the delivery of interventional devices and infusion of diagnostic agents, such as contrast media, into the neuro vasculature during diagnostic and/or therapeutic procedures. It is not intended for use in peripheral or coronary vasculature.

The Indications for Use statement of the subject device is the same as that of the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 2: Comparison of technological characteristics of the pNOVUS 21 Microcatheter and predicate device pNOVUS 21 Microcatheter

Parameter	Predicate Device K221279	Subject Device K242420	Justification of Substantial Equivalence
Device Name	pNOVUS 21 Microcatheter	pNOVUS 21 Microcatheter	N/A
Model #	PNOV-21-160	PNOV-21-160 PNOV-21-150	N/A
510(k) Number	K221279	K242420	N/A
Product Classification	21 CFR 870.1200, 21 CFR 870.1250 Class II	21 CFR 870.1200, 21 CFR 870.1250 Class II	Same as predicate
Product Codes	DQO, QJP	DQO, QJP	Same as predicate
Device Design/Materials	Stainless steel braided shaft, polymeric exterior	Stainless steel braided shaft, Nitinol coil, polymeric exterior	Similar to predicate. The subject device also includes a nitinol coil. This is a commonly used component in medical devices.
Marker Band Material/Radiopacity	Radiopaque Platinum/Iridium	Radiopaque Platinum/Iridium	Same as predicate
Adhesives Used	Acrylated Urethane and Cyanoacrylate	Acrylated Urethane and Cyanoacrylate	Same as predicate
Hub Material	Polyamide	Polyamide	Same as predicate
Coating	Distal: Hydrophilic coating Proximal: N/A Length: 550 mm	Distal: Hydrophilic coating Proximal: N/A Length: 1000 mm	Similar to the predicate. The difference in coating lengths does not raise new questions of safety and effectiveness.
Mode of Action	Physical	Physical	Same as predicate
Principle of Operation	The device is advanced into the vasculature over an appropriately sized guidewire. Once the microcatheter is inserted, it can be advanced through the vasculature to the desired location.	The device is advanced into the vasculature over an appropriately sized guidewire. Once the microcatheter is inserted, it can be advanced through the vasculature to the desired location.	Same as predicate

Effective Length	160 cm	150cm 160cm	Similar to the predicate. Shorter length variant is also offered for the subject device.
Outer Diameter:			Similar to the predicate.
Proximal	2.7F	2.7F	
Distal	2.4F	2.5F	
Inner Diameter	0.021"	0.021"	Same as predicate
Use	Single Use Device	Single Use Device	Same as predicate
Sterilization	Ethylene Oxide	Ethylene Oxide	Same as predicate
Biocompatible	Yes	Yes	Same as predicate
Shelf Life	1 year	1 year	Same as predicate
Accessory Devices	Introducer Sheath, Shaping Mandrel	Introducer Sheath, Shaping Mandrel	Same as predicate
Intended Use Environment	Healthcare facility/hospital. Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Rx only – device restricted to sale by or on order of a physician.	Healthcare facility/hospital. Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Rx only – device restricted to sale by or on order of a physician.	Same as predicate
Packaging Components/Configuration	Device is stored within a HDPE Packaging Hoop with Tubing Clips, sealed within a Tyvek Pouch, which is then packaged in a product carton.	Device is stored within a HDPE Packaging Hoop with Tubing Clips, sealed within a Tyvek Pouch, which is then packaged in a product carton.	Same as predicate

VII. PERFORMANCE DATA

Biocompatibility

Biocompatibility testing for the subject pNOVUS 21 Microcatheter was conducted based on International Organization for Standardization (ISO) 10993-1:2018 "Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process," and the US FDA guidance document "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process"" (2020). The Introducer Sheath (P1066) and Shaping Mandrel (P1142) accessories remain unchanged since prior clearance under K221279.

Table 3 below summarizes biocompatibility testing performed on the pNOVUS 21 Microcatheter.

Table 3: Biocompatibility Testing Results for pNOVUS 21 Microcatheter

Test	Test Description	Conclusion
pNOVUS 21 Test Results		
Cytotoxicity ISO 10993-5	MTT- L929 fibroblast cells	No cytotoxic effect.
Sensitization ISO 10993-10	Magnusson-Kligman Maximization	No sensitization indicated.
Skin irritation ISO 10993-10 ISO 10993-23	Intracutaneous Reactivity (ISO)	No sensitization indicated.
Systemic toxicity ISO 10993-11	Systemic Injection (ISO)	No acute systemic toxicity indicated.
	Material Mediated Pyrogenicity test	pNOVUS 21 is deemed non-pyrogenic.
Hemocompatibility ISO 10993-4	Hemolysis (ASTM method) indirect extract	No hemolysis indicated.
	Hemolysis (ASTM method) direct contact	No hemolysis indicated.
	Complement activation	No complement activation indicated.
	In Vitro Thrombogenicity Blood Loop Assay	pNOVUS 21 is deemed thromboresistant.
	Partial Thromboplastin Time (PTT)	Similar thrombogenic effect as the predicate device.
	Platelet and Leukocyte Count	Similar thrombogenic effect as the predicate device.

Sterilization

The pNOVUS 21 Microcatheter is sterilized by Ethylene Oxide gas. Sterilization takes place in Trier, Germany by Rose GmbH.
The pNOVUS 21 has been adopted into an existing validated cycle per I.E. EN ISO 11135:2014 & A1:2019 and AAMI TIR28:2016.

Standards utilized in regards to sterilization:
ISO 11135:2014 & A1:2019 "Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices"
FDA guidance documents utilized in regards to sterilization:
"Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labelled as Sterile" (2016)

The sterilization cycle has been validated via the half cycle method.

Shelf Life

Shelf life conditioning has been completed and testing has been performed on devices subjected to the accelerated aging (AA) process to represent 1 year of aged units. Devices subjected to 1 year AA were tested to ensure design and performance specification requirements were met after the one year shelf life that pNOVUS 21 Microcatheter will have at commercialization.

FDA Guidance Documents utilized in regards to shelf life:
"Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019)
"Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters - Class II Special Controls Guidance for Industry and FDA" (2010)

Non-Clinical Performance Data

The following non-clinical performance tests were performed to support the substantial equivalence determination. These are summarized below.

PERFORMANCE TESTING - BENCH

A full suite of performance testing on the bench was carried out on pNOVUS 21. The results of this testing demonstrated compliance to all the design attributes and that the device performs as intended. The results of these tests, in conjunction with the substantial equivalence claims as outlined in the premarket notification, demonstrate substantial equivalence to the cited predicate device. Table 4 below summarizes the tests and results.

Table 4: Summary of Non-Clinical Bench Testing

Test	Test Method Summary	Results
Catheter Static Burst Pressure Test Under Static Conditions	The catheter was tested for static burst pressure under static conditions as per ISO 10555-1 Annex F, until failure (until burst or leak). The catheter must exceed a specified minimum pressure.	All samples met the acceptance criteria that the hub or any other part of the catheter shall not leak when pressurized to failure below a minimum specified pressure. This is in line with the predicate device, thus, supporting substantial equivalence.

Hydrophilic Coating Lubricity	The catheter hydrophilic coating lubricity is tested by applying a pinch force to the coated section of the catheter. The friction force shall be below the specified maximum friction value for that segment.	All samples met the acceptance criteria. The pNOVUS 21 was found to be comparable to similar marketed devices.
Particulate Matter	The catheter particulate matter was tested by calculating the size and number of particulates generated during simulated use of the device in a neurovascular model.	Particulate testing was performed on the pNOVUS 21, predicate, and similar marketed devices. pNOVUS 21 met the acceptance criteria of similar or less particulates than the predicate device or similar marketed device.
Torque Strength	The catheter was evaluated for torque strength by rotating the specimen until failure, the catheter must exceed a specified minimum number of rotations.	All samples met the acceptance criteria. Both the subject device and the predicate were tested to same acceptance criteria.
Flow Rate at Maximum Rated Infusion Pressure	The flow rate at the maximum rated infusion pressure was measured using the following injectate media: saline, 50/50 mix of saline and contrast medium.	All samples met the acceptance criteria. The mean flow rate values for the pNOVUS 21 and similar marketed devices are comparable for the injectate media tested.
Radio-Detectability	The catheter is visualized under fluoroscopy.	All samples passed the acceptance criteria. pNOVUS 21 and the predicate device were imaged showing equivalence in terms of radiopacity.
Maneuverability / Trackability	The device is tested for its ability to reach target site in a neurovascular model.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Pushability	A force is applied to the shaft of the catheter in order to deliver it to the target site without kinking or damage to the catheter.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Kink Resistance	The catheter is tested at different locations for its ability to bend to clinically relevant radii without kinking.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Lumen Patency	The device is subjected to simulated use in a neurovascular model and the lumen inspected for damage.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Tip Profile	The distal tip of the device is inspected for defects.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Dimensional (Inner Diameter (ID), Outer Diameter (OD), Effective Length, Tip Length)	The dimensions of the catheter and the catheter tip are measured.	All samples met the acceptance criteria, confirming the device meets specifications to ensure it performs as intended.
Tip Shapeability	The distal tip of the catheter is shaped using the shaping mandrel supplied with pNOVUS 21.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.

Flexural Fatigue	The catheter is inspected for damage following insertions and withdrawals in a simulated use neurovascular model.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Hydrophilic Coating Length	The length of the coated area of the catheter is measured.	All samples met the acceptance criteria, confirming the device meets specifications to ensure it performs as intended.
Hydrophilic Coating Integrity	The coated length of the device is inspected for damage post simulated use and flexural fatigue testing. Results are compared to a baseline taken prior to testing.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Tensile Strength	The catheter is tested to failure under tensile force following pre-conditioning by tracking through a tortuous path model.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Chemical Compatibility	The ID and OD of the catheter are inspected for damage following exposure to media.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Interventional Device Compatibility	The catheter is inspected for damage post simulated use testing with compatible interventional devices in a neurovascular model.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
2nd Microcatheter	A second microcatheter with a specified OD in parallel with the pNOVUS 21 is tested under simulated use conditions in a guide catheter with a specified ID.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Visual Inspection	The catheter surface, including hydrophilic coated segment, is inspected for extraneous matter and surface defects under magnification.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Air Leakage During Aspiration	The catheter is tested for air leakage during aspiration using a syringe attached to the hub.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Pressure Fatigue	The catheter is pressurized to the maximum rate infusion pressure following 5 power injection cycles at the maximum rated infusion pressure.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Maximum Infusion Pressure	The catheter is pressurized to the maximum infusion pressure.	All samples met acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Ancillary Device Compatibility	Simulated use testing is performed to verify compatibility with the compatible device recommendations included in the device labelling.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.

Hub/Luer Fitting	The catheter hub is tested per ISO 80369-7.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Packaging Configuration	During simulated use testing, the configuration of the packaging is verified as per specification.	All samples met the acceptance criteria, confirming the device meets specifications to ensure it performs as intended.
Dispenser Hoop	During simulated use testing, the presence of a female luer and retention clip on each of the dispenser hoops is verified.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Hub/Luer Markings	The hub of the catheter is inspected to ensure all required identifiers are present.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Directions for Use (DFU)	During simulated use testing, the presence of a DFU with each device is verified.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Usability	The usability of the pNOVUS 21 was assessed per FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices" and EN 62366 "Medical Devices - Part 1: Application for Usability Engineering to Medical Devices."	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Corrosion Resistance	The pNOVUS 21 is visually inspected for signs of corrosion post exposure to required conditions.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.

Standards utilized in regards to bench testing:

ISO 10555-1:2013/A1:2017 “Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements”

ISO 80369-20 “Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods”

ISO 80369-7:2016 “Small-bore connectors for liquids and gases in healthcare application - Part 7: Connectors for intravascular or hypodermic applications”

ISO 62366-1: 2015 + AC:2015 &A1 2020 “Medical Devices- Part 1: Application of Usability Engineering to Medical Devices”

ASTM F640-12 “Standard Test Methods for Determining Radiopacity for Medical Use”

FDA Guidance Documents utilized in regards to bench testing:

“Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling” (2019)

“Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters - Class II Special Controls Guidance for Industry and FDA” (2010)

“Applying Human Factors and Usability Engineering to Medical Devices” (2016)

Animal Study

Animal testing was not performed on the pNOVUS 21 Microcatheter as successful completion of non-clinical performance testing was deemed sufficient to establish substantial equivalence.

Clinical Testing

Clinical testing was not performed on the pNOVUS 21 Microcatheter as no human studies were deemed necessary to establish substantial equivalence.

VIII. CONCLUSIONS

Phenox Ltd has demonstrated that the subject pNOVUS 21 Microcatheter is substantially equivalent to the predicate pNOVUS 21 Microcatheter (K221279). The subject device has the same intended use, similar technological characteristics, similar materials, and same operating principles as the predicate device. The differences do not raise new questions of safety or effectiveness. The subject device has been demonstrated to perform as intended through successful non-clinical performance testing.