December 1, 2023

Anoxia Medical, Inc.
% Bosmat Friedman, MSc
Regulatory Consultant
ProMedoss, Inc.
3521 Hatwynn Road
Charlotte, North Carolina 28269

Re: K231179
Trade/Device Name: Slinky Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY, DQO
Dated: November 1, 2023
Received: November 1, 2023

Dear Bosmat Friedman:

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,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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OHT5: Office of Neurological
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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)*
K231179

Device Name
Slinky Catheter

Indications for Use *(Describe)*
The Slinky Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate introduction of diagnostic agents and therapeutic devices. It is not intended for use in coronary arteries.

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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510(k) Summary

510(k) Number: K231179

Date Prepared: November 30, 2023

Submitter/Manufacturer	Anoxia Medical, Inc. 3475 Investment Boulevard, Suite #9 Hayward, CA 94545
Contact	Henry Nita Telephone: 650-430-2045
Trade Name	Slinky Catheter
Common/Usual Name	Distal Access Catheter
Regulation Description	Percutaneous Catheter
Regulation Number	21 CFR 870.1250; 21 CFR 870.1200
Product Code	QJP, DQY, DQO
Device Class	Class II
Classification Panel	Neurology, Cardiovascular
Predicate Devices	SOFIA PLUS/Distal Access Catheters (K150366)

Device Description:

The Slinky® Catheter is a single lumen, variable stiffness catheter with a coil and braid reinforcement. It has a radiopaque marker at the distal tip for enhanced fluoroscopic visualization, a lubricious inner liner, and a hydrophilic coating on the distal 35 cm to enhance lubricity and vascular navigation. The Slinky® Catheter is provided sterile via Ethylene Oxide (EO) sterilization, non-pyrogenic, and is for single use only.

Indications for Use:

The Slinky Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate introduction of diagnostic agents and therapeutic devices. It is not intended for use in coronary arteries.

Comparison of Technological Characteristics with the Predicate Device:

The Slinky® Catheter has similar indications for use and technological characteristics as the predicate device as presented in the following table. The differences do not raise new questions of safety or effectiveness.

Comparison to the Predicate Device		
Characteristic	**Predicate Device SOFIA PLUS/Distal Access Catheters K150366**	**Subject Device Slinky® Catheter K231179**
Classification, Product Code	Class II, DQY, DQO	Class II, QJP, DQY, DQO
Generic Name	Percutaneous Catheter	Same
Regulation Number	21 CFR 870.1250; 21 CFR 870.1200	Same
Classification Panel	Neurology, Cardiovascular	Same
Indications For Use	The SOFIA PLUS/Distal Access Catheters are indicated for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.	The Slinky Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate introduction of diagnostic agents and therapeutic devices. It is not intended for use in coronary arteries.
DIMENSIONS:		
Catheter Size	6F	6F
Catheter Effective Length	115-135 cm	132 cm
Proximal ID	0.070”	0.075”
Proximal OD	0.0825”	0.086”
Tip Configuration	Steam shapeable by user	Straight-cut or 30°-cut atraumatic soft tip configurations
MATERIALS:		
Catheter Body Outer Layer	Polyurethane elastomer (Polyblend and Pellethane), polyether block amide (Pebax) and polyamide (Grilamid)	Pebax® 55D, Pebax® 63D, Grilamid™ L25, QFLEX 85A/Polyblend 60A, Pellathane® 80A, Pebax® 35D
Catheter Body Inner Layer	Stainless steel braid/coil, PTFE and polyolefin elastomer	Braid and coil: 304 V Stainless Steel, PTFE, QFLEX 75A/Polyblend 60A
Marker	Platinum/Iridium	Platinum/Iridium
Hub	Nylon	Acrylic
Strain Relief	Polyurethane	Polyolefin
Shaping Mandrel	Stainless steel	N/A
Coating	Hydrophilic coating: Hydak®	Hydrophilic coating: Harland
Guidewire Compatibility	0.035”	0.014”, 0.035”, 0.038”
Method of Supply	Sterile and Single Use	Same

Sterilization Method	Ethylene oxide	Same
Packaging Card	Polyethylene	Same
Packaging Hoop	HDPE	Polyethylene
Packaging Pouch	Tyvek®	Nylon and LDPE (top) Tyvek® 1073B (bottom)
Packaging Carton Box	Pouch and IFU placed in carton box	Same
Shelf Life	Not specified	12 Months
Accessories Included	Introducer sheath, shaping mandrel	None

Performance Testing:

To demonstrate the substantial equivalence of the subject Slinky® Catheter to the predicate device, the SOFIA PLUS/Distal Access Catheters, the performance, biocompatibility, and sterility of the Slinky® Catheter were evaluated via the following tests and assessments:

- Design Verification Bench Testing
- Biocompatibility
- Shelf-Life
- Sterilization
- Packaging Validation

Bench Performance Testing

Test	Test Method Summary	Conclusions
Simulated Use	Test articles were used by three trained interventional neuroradiologists in a tortuous anatomical bench test model, demonstrating compatibility with ancillary devices including introducers, microcatheters, and guidewires.	Device performed as intended under simulated use conditions.
Particulate Test	Test articles were tracked multiple times through the tortuous anatomical model with ancillary devices. Devices were inspected for coating anomalies pre- and post-testing.	Particulate generation of the subject device was similar to the predicate device.
Product Compatibility	Simulated use testing by three physicians was conducted, using a full-length silicone anatomical tortuous path model. The procedure included using the test catheter along with worst case ancillary devices (i.e., smallest ID introducer, largest OD guidewire, stiff micro guidewire, large stent-retriever).	The device was found to be compatible with ancillary devices.
Dimensional and Visual Attributes	The physical and dimensional attributes were evaluated and measured.	Device met the established dimensional and visual specifications.

Test	Test Method Summary	Conclusions
Kink Resistance	The distal, mid, and proximal sections of the catheter were wrapped around varying size pin gauges.	Device met the established kink resistance criteria.
Radio Detectability	The distal marker band and catheter body visibility were evaluated under fluoroscopy.	Device radiopacity comparable to the predicate device.
Catheter Hub	The hub functionality was evaluated during simulated use, freedom from leakage, flow rate, dynamic burst, particulate, and other bench testing completed.	Device hub meets the requirements of ISO 80369-7.
Durability/Lubricity of Hydrophilic Coating	Lubricious coating on the catheter surface was evaluated after simulated use for defects and for friction force.	Device met the established friction and lubricity criteria. The friction force was similar to the predicate.
Tip Flexibility	Device tip stiffness was characterized on a cantilever bend test.	The tip stiffness was similar to the predicate.
Torque Strength	Devices were pre-conditioned by simulated use and torqued to failure inside a tortuous anatomical model with the distal tip held fixed.	Device torque strength is the same as the predicate device.
Force at Break (Distal and Hub)	Catheter force at break averaged 8 lbf for the hub and 5-6 lbf for the mid and distal segments and exceeds acceptance criteria determined from withdrawal force measurements.	Tensile strength meets the test acceptance criteria.
Flow Rate	Flow rate was characterized at 100 psi with diagnostic agents (e.g., saline, contrast media).	Device meets the specified requirements for delivery of diagnostic agents.
Static Burst Pressure	Device can withstand static pressure above labeled 100 psi maximum with margin of safety.	Device integrity is suitable for intended clinical use and met requirements of ISO 10555-1.
Freedom from Leakage	Testing followed the methods and criteria defined in EN ISO 10555-1 after pre-conditioning by simulated use.	Device integrity is suitable for intended clinical use and met requirements of ISO 10555-1.
Air Leakage	No air leakage at hub into syringe for 15 seconds.	Device integrity is suitable for intended clinical use and met requirements of ISO 10555-1.
Dynamic Burst	Devices were pre-conditioned by simulated use. Test devices were then connected to a pressurized fluid source, starting with 250 psi and further increased every 10 seconds until a maximum of 600 psi was applied.	Device met labeled maximum infusion pressure of 100 psi.
Peak Tensile Force	Devices were pre-conditioned by simulated use. Tensile testing was then conducted per the methods defined in EN ISO 10555-1.	Device met acceptance criteria determined from withdrawal force testing.

Biocompatibility

Biocompatibility was assessed in accordance with ISO 10993-1 guidelines for a limited exposure (< 24 hours), externally communicating device with circulating blood contact. All studies were conducted according to 21 CFR Part 58 Good Laboratory Practices.

Test	Test Method Summary	Conclusions
Cytotoxicity (ISO 10993-5) - MEM Elution Assay	Cell culture observed for cytotoxic reactivity following exposure to test extract with Grade ≤2 as acceptable.	Non-cytotoxic
Sensitization (ISO 10993-10) - Guinea Pig Maximization Sensitization	Observation of study animals exposed to test extracts for delayed dermal sensitization.	No sensitization reaction
Irritation (ISO 10993-10) - Intracutaneous Reactivity	Observations for dermal reactivity were conducted at 24, 48, and 72 hours after test extract injection. Test article sites should not show a significantly greater biological reaction than sites injected with control article.	Non-irritant
Acute Systemic Toxicity (ISO 10993-11)	Study animals injected with the subject device observed for abnormal clinical signs indicative of toxicity during the 72-hour test period.	No signs of toxicity
Pyrogenicity (USP <151>, ISO 10993-11)	Study animals observed for individual temperature rise following intravenous injection of test extracts.	Non-pyrogenic
Hemolysis (ASTM F756, ISO10993-4) – Direct and Indirect (extract) Hemolysis	The difference between the hemolytic indexes of the subject device and the negative control was evaluated after exposure to test extracts and direct exposure to test article.	Direct contact - Non-hemolytic Indirect contact - Non-hemolytic
SC5b-9 Complement Activation Assay (ISO 10993-4)	Using an enzyme immunoassay, SC5b-9 concentration following exposure of test article extracts to normal human serum (NHS) compared to SC5b-9 concentration of the control article exposed to NHS.	Not considered to be a potential activator of the complement system
Thrombogenicity (ASTM F2382) - Partial Thromboplastin Time Platelet and Leukocyte Count (ASTM F2888-19, ISO 10993-4) In vitro Blood Loop Assay	Thrombogenicity potential of test article compared to control articles.	Acceptable results

Sterilization and Shelf-Life

The Slinky® Catheter is labeled as a single-use sterile device with shelf-life of 12 months. The sterilization process has been validated and process monitoring controls are in place to assure that the device is EO sterilized to achieve a minimum sterility assurance level (SAL) of 10^{-6}. Shelf-life studies have been conducted and demonstrate that the product and packaging remain functional and sterile for the shelf-life period of 12 months.

Conclusion:

The Slinky® Catheter has the same intended use and similar technological characteristics and principles of operation as the currently marketed predicate SOFIA PLUS/Distal Access Catheters. Any differences between the subject and predicate device do not raise new questions of safety and effectiveness. The subject device was evaluated through design verification and validation, biocompatibility, and sterility testing. Based on the information submitted in this 510(k) submission, the subject Slinky® Catheter is substantially equivalent to the currently marketed predicate SOFIA PLUS/Distal Access Catheters.