July 13, 2026

Balt USA, LLC
Subha Elango
Manager, Regulatory Affairs
29 Parker
Irvine, California 92618

Re: K260199
Trade/Device Name: SLIM Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY, KRA
Dated: June 12, 2026
Received: June 15, 2026

Dear Subha Elango:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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, PhD
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
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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)*
K260199

Device Name
SLIM Microcatheter

Indications for Use *(Describe)*
The SLIM Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and to assist in the delivery of interventional devices in the neurovasculature.

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

510(k) Summary: K260199

Applicant:	Balt USA, LLC 29 Parker Irvine, CA 92618 Registration No: 3014162263
Contact Person:	Subha Elango Manager, Regulatory Affairs Email: subha.elango@baltgroup.com
Date Summary Prepared:	June 12, 2026
Trade Name:	SLIM Microcatheter
Common Name:	Percutaneous Catheter
Review Panel:	Neurology, Cardiovascular
Product Code:	QJP, DQY, KRA
Regulation Number:	21 CFR 870.1250, 21 CFR 870.1210
Device Classification:	Class II
Predicate Device:	Phenom Catheters 510(k) #: K210230
Reference Device:	NG Delivery Catheter 510(k) #: K230609 Headway Duo Microcatheter 510(k) #: K120917

Device Description:

The SLIM Microcatheter is a single lumen, variable stiffness, composite microcatheter. The design facilitates the advancement of the microcatheter and is intended to assist in the delivery of interventional devices in the neurovasculature. The outer surface of the SLIM Microcatheter is coated with a hydrophilic coating to increase lubricity. The proximal end of the SLIM Microcatheter incorporates a luer fitting for the attachment of accessories. A total of three (3) radiopaque markers are built into the microcatheter - two (2) radiopaque markers at the distal end help to facilitate fluoroscopic visualization and one (1) marker 3cm from the distal tip to facilitate the delivery of embolization coils.

A Steam Shaping Mandrel and Peel-away Introducer Tube are included within the tray.
The SLIM Microcatheter is provided sterile, non-pyrogenic, and is intended for single use only.

Indications for Use:

The SLIM Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and to assist in the delivery of interventional devices in the neurovasculature.

Device Comparison:

Device Attribute	Predicate Device Phenom Catheters **K210230**	Reference Device Headway Duo Microcatheter **K120917**	Reference Device NG Delivery Catheter **K230609**	Subject Device SLIM Microcatheter **K260199**
Indications for Use	Phenom™ Catheters are intended for the introduction of interventional devices or diagnostic agents into the neuro, peripheral, and coronary vasculatures.	The Headway Duo Microcatheter is intended for general intravascular use, including the peripheral and coronary vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials. The Headway Duo Microcatheter is intended for neurovascular use, for the infusion of diagnostic agents, such as contrast media, and therapeutic agents that have been cleared or approved for use in the neurovasculature and are compatible with the inner diameter of the Headway Duo Microcatheter.	The NG Delivery Catheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and to assist in the delivery of interventional devices, such as distal access catheters, in the neurovasculature.	The SLIM Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and to assist in the delivery of interventional devices in the neurovasculature.
FDA Product Code	DQY; KRA; QJP	DQO	QJP; DQY	QJP; DQY; KRA
Dimensional Attributes				
Inner Diameter	0.017" – 0.0445"	0.0165"	0.021"	0.017"
Shaft Outer Diameter	Proximal: 2.2 F – 4.7 F (0.029" – 0.061") Distal: 1.8 F – 4.2 F (0.024" – 0.055")	2.1 F (0.028")	0.059" – 0.069"	0.034"
Effective Length	120 cm – 160 cm	157 cm and 168 cm	152 cm	150 cm, 160 cm, 170 cm
Coating Length	90 cm – 100 cm	115 cm	60 cm	60 cm
Materials	Commonly used medical grade plastics & metals with hydrophilic coating	Same as K210230	Same as K210230	Same as K210230
Marker band	1 or 2 tip markers	2 tip markers	2 marker bands	3 marker bands
Packaging/Condition Supplied				
Condition	Sterile and Single Use	Same as K210230	Same as K210230	Same as K210230

Device Attribute	Predicate Device Phenom Catheters **K210230**	Reference Device Headway Duo Microcatheter **K120917**	Reference Device NG Delivery Catheter **K230609**	Subject Device SLIM Microcatheter **K260199**
Supplied				
Sterilization Method	Ethylene Oxide (EO), SAL 10^{-6}	Same as K210230	Same as K210230	Same as K210230
Packaging Configuration	For the hoop configuration, the catheter is placed in a dispenser hoop and packaged in a pouch. For the tray configuration, the dispenser-hooped catheter and its accessories are placed in a tray, which is then sealed in the pouch. The pouch is then placed inside a carton box.	Catheter is placed in a dispenser hoop and accessories on a card that is then inserted into the pouch. The pouch is then placed inside a carton box.	Catheter is placed in a dispenser hoop and accessories on a mounting card that is then inserted into the pouch. The pouch is then placed inside a carton box.	Same as K230609
Shelf-Life	12 months	Not available	12 months	Same as K210230

Non-Clinical Performance Testing:

Biocompatibility:

A biocompatibility assessment was conducted for the SLIM Microcatheter in accordance with the FDA biocompatibility guidance, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"," issued on September 8, 2023.

The subject device is an externally communicating device directly contacting circulating blood for a limited (≤ 24 hours) duration and the device was assessed for cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, material-mediated pyrogenicity, direct and indirect hemolysis, complement activation, and thrombogenicity.

Performance Data – Bench Testing:

The following performance bench tests were conducted to assess the performance of the SLIM Microcatheter.

Test	Test Method Summary	Results
Dimensional Verification	Measurements taken to verify that the device meets dimensional specifications.	Pass
Visual Inspection	Visual inspection was conducted for surface defects.	Pass
Tensile Strength	Peak tensile force was evaluated per ISO 10555-1 after preconditioning in a simulated use model.	Pass
Kink Resistance	Kink resistance was evaluated after preconditioning in a simulated use model.	Pass

Test	Test Method Summary	Results
Liquid Leak	The device was exposed to a liquid pressure for 30 seconds. The device was inspected for leakage per ISO 10555-1.	Pass
Air Leakage	The device was tested for air leakage into the hub per ISO 10555-1.	Pass
Dynamic Burst	Tested to verify the device can withstand internal liquid pressure under dynamic flow conditions with the distal end open.	Pass
Static Burst	The distal tip of the catheter was blocked, and fluid was injected into the lumen at increasing pressure until the catheter burst per ISO 10555-1 and the static burst pressure was compared with the maximum pressure generated with manual syringe injection.	Pass
Turns to Failure (Torque Strength)	The device was evaluated for torque strength by measuring the number of catheter rotations until failure after preconditioning in a simulated use model.	Pass
Hub Verification	The device shall meet the functional requirements with established acceptance criteria per ISO 80369-7.	Pass
Particulate Matter	The catheter underwent simulated use testing and particulate testing was conducted including the predicate device for comparison.	Pass
Tip Buckling	The maximum force to cause catheter tip buckling while constrained at varying distances from the tip was measured.	The tip stiffness was comparable to the predicate and other cleared catheters.
Coating Integrity	The coating integrity was inspected before and after preconditioning in a simulated use model.	No evidence of surface damage or coating defects.
Contrast and Saline Exposure	After the device was used to deliver saline and contrast media, the device was inspected for damage, and dimensional attributes were measured.	No visual evidence of damage or dimensional changes.
Radiopacity	Tested to verify that radiopaque markers are visible using standard fluoroscopic equipment.	Pass
Flow Rate	The flow rate of contrast media and saline and associated injection pressures were evaluated.	The flow rate was characterized.

Test	Test Method Summary	Results
Design Validation/Usability	The subject and predicate devices were prepared in accordance with their respective instructions for use and tested for device usability in a clinically relevant anatomical model.	Device preparation, introduction, trackability, and retrieval were comparable to the predicate.
Compatibility – Interventional Devices	The subject device was evaluated for compatibility with interventional devices such as guidewires, neurovascular embolization coils, DMSO, and liquid embolic agents. Compatibility with DMSO and liquid embolic agents was established through risk assessment and testing with DMSO and representative liquid embolic agents, including the SQUID™ Liquid Embolic Agent and TRUFILL™ n-Butyl Cyanoacrylate (n-BCA) Liquid Embolic System.	The subject device is compatible for use with guidewires, neurovascular embolization coils, DMSO and liquid embolic agents.

Performance Data – Animal:
No animal study was deemed necessary. A determination of substantial equivalence is based on successful completion of non-clinical bench testing.

Clinical Testing:
No clinical study was deemed necessary. A determination of substantial equivalence is based on successful completion of non-clinical bench testing.

Conclusion:
Based on the same intended use, similar technological characteristics, and the results of the nonclinical testing, the subject device is found to be substantially equivalent to the predicate device. The differences in technological characteristics do not raise new questions of safety and effectiveness. Non-clinical testing was conducted to demonstrate that the subject device meets the specifications and performs as intended.