June 3, 2025

Balt USA, LLC
Catherine Chiou
Senior Regulatory Affairs Specialist
29 Parker
Irvine, California 92618

Re: K243948
Trade/Device Name: Raptor Aspiration Catheter; Balt Aspiration Tubing Set
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: May 2, 2025
Received: May 2, 2025

Dear Catherine Chiou:

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
Physical Medicine 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)*
K243948

Device Name
Raptor Aspiration Catheter; Balt Aspiration Tubing Set

Indications for Use *(Describe)*

Raptor Aspiration Catheter:
The Raptor Aspiration Catheter with a compatible aspiration pump and Balt Aspiration Tubing Set is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.

Balt Aspiration Tubing Set:
The Balt Aspiration Tubing Set is intended to connect the Raptor Aspiration Catheter to the canister of a compatible aspiration pump and to allow the user to control the fluid flow.

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.

510(k) Summary: K243948

Applicant:	Balt USA, LLC 29 Parker Irvine, CA 92618 Registration No.: 3014162263
Contact Person:	Catherine Chiou Senior Specialist, Regulatory Affairs Email: Catherine.chiou@baltgroup.com

Date Summary Prepared:	May 30, 2025
Trade Name:	Raptor Aspiration Catheter; Balt Aspiration Tubing Set
Common Name:	Catheter, Thrombus Retriever
Review Panel:	Neurology
Product Code:	NRY
Regulation Number:	21 CFR 870.1250
Regulation Name:	Percutaneous Catheter
Device Classification:	Class II
Predicate Device:	ZOOM (71, 55, 45, 35) Reperfusion Catheters; ZOOM Aspiration Tubing 510(k)#: K210996
Reference Device:	Next Generation Aspiration Catheter; Balt Aspiration Tubing Set 510(k)#: K234083

Device Description:
The Raptor Aspiration Catheter is a single-lumen, variable stiffness composite catheter offered in various sizes that facilitates removal of thrombus from the neurovasculature when connected to a compatible aspiration pump and the Balt Aspiration Tubing Set. The distal tip of the catheter shaft includes a markerband and the proximal end of the catheter has a luer fitting to allow for the attachment of ancillary devices for navigation, infusion of fluids, and aspiration through the catheter. The Raptor Aspiration Catheter distal shaft has an external hydrophilic coating which provides a lubricious surface during use. The Raptor Aspiration Catheters are compatible with 0.014" – 0.018" guidewires.

A peelable split Introducer Sheath is provided in the package to provide support and facilitate the introduction of the distal tip of the Raptor Aspiration Catheter into an appropriate vascular sheath. The catheter and Introducer Sheath are provided sterile, non-pyrogenic, and intended for single use only.

The Balt Aspiration Tubing Set consists of one 100" HPF proximal tubing with a suction connector on one end and male rotator on the other, one 1-way Large Bore Stopcock, and one 10" HPF distal tubing with a female luer connector on one end and a male rotator on the other.

The Balt Aspiration Tubing Set facilitates the supply of vacuum from a compatible aspiration pump to the distal tip of the Raptor Aspiration Catheter. Balt Aspiration Tubing Set is provided sterile, non-pyrogenic and it is intended for single use only

Indications for Use:

Raptor Aspiration Catheter:
The Raptor Aspiration Catheter with a compatible aspiration pump and Balt Aspiration Tubing Set is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.
Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.

Balt Aspiration Tubing Set:
The Balt Aspiration Tubing Set is intended to connect the Raptor Aspiration Catheter to the canister of a compatible aspiration pump and to allow the user to control the fluid flow.

Comparison of Technological Characteristics:

	Predicate Device	**Reference Device**	**Subject Device**
	ZOOM (71, 55, 45, 35) Reperfusion Catheters; ZOOM Aspiration Tubing (K210996)	**Next Generation Aspiration Catheter; Balt Aspiration Tubing Set (K234083)**	**Raptor Aspiration Catheter; Balt Aspiration Tubing Set (K243948)**
Indications for Use	The ZOOM Reperfusion Catheters, with the ZOOM Aspiration Tubing and ZOOM Aspiration Pump (or equivalent vacuum pump), are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. The ZOOM Aspiration Tubing is intended to connect the ZOOM Reperfusion Catheter to the ZOOM Canister of the ZOOM Aspiration Pump and to allow the user to control the fluid flow.	Next Generation Aspiration Catheter: The Next Generation Aspiration Catheter with a compatible aspiration pump and Balt Aspiration Tubing Set is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV-tPA) or who fail IV-tPA therapy are candidates for treatment. Balt Aspiration Tubing Set: The Balt Aspiration Tubing Set is intended to connect the Next Generation Aspiration Catheter to the canister of a compatible aspiration pump and to allow the user to control the fluid flow.	Raptor Aspiration Catheter: The Raptor Aspiration Catheter with a compatible aspiration pump and Balt Aspiration Tubing Set is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment. Balt Aspiration Tubing Set: The Balt Aspiration Tubing Set is intended to connect the Raptor Aspiration Catheter to the canister of a compatible aspiration pump and to allow the user to control the fluid flow.

	Predicate Device	Reference Device	Subject Device
	ZOOM (71, 55, 45, 35) Reperfusion Catheters; ZOOM Aspiration Tubing (K210996)	**Next Generation Aspiration Catheter; Balt Aspiration Tubing Set (K234083)**	**Raptor Aspiration Catheter; Balt Aspiration Tubing Set (K243948)**
Device Classification/ Product Code	Class II / NRY (Percutaneous Catheter)	Same as K210996	Same as K210996
Intended Use	Revascularization of patients with acute ischemic stroke.	Same as K210996	Same as K210996
Dimensional Specifications			
Inner Diameter	0.035" – 0.071"	0.071"and 0.074"	0.038" and 0.054"
Outer Diameter	Proximal: 0.061" – 0.083" Distal: 0.051" – 0.083"	Proximal: 0.083" and 0.086" Distal: 0.082" and 0.085"	Proximal: 0.062" and 0.074" Distal: 0.051" and 0.067"
Effective Length	137 cm – 160 cm	128 cm, 132 cm and 120 cm, 132 cm	145 – 160 cm and 125 – 150 cm
Device Attributes			
Materials	Commonly used medical grade plastics and metals with hydrophilic coating.	Same as K210996	Same as K210996
Coating	Hydrophilic	Same as K210996	Same as K210996
Packaging Configuration	The catheter is placed in a protective polyethylene tube and then mounted, along with the accessories, onto a polyethylene packaging card. The packaging card is inserted into a Tyvek® pouch which is then sealed. The sealed pouch and IFU are placed in a carton box.	Same as K210996	Same as K210996
Shelf Life	12 months	Same as K210996	Same as K210996
Sterilization			
Condition Supplied	Sterile and Single Use	Same as K210996	Same as K210996
Method	Ethylene Oxide (EO), SAL 10^{-6}	Same as K210996	Same as K210996
Accessories			
Accessories	RHV	Introducer Sheath	Same as K234083
Aspiration Tubing	ZOOM Aspiration Tubing	Balt Aspiration Tubing Set	Same as K234083
Dimensional Specifications	Length: 104" Inner Diameter: 0.110" Minimum	Length: 114" Inner Diameter: 0.110" ± 0.003"	Same as K234083
Condition Supplied	Sterile and Single Use	Same as K210996	Same as K210996
Sterilization Method	Ethylene Oxide (EO), SAL 10^{-6}	Same as K210996	Same as K210996
Flow Control Mechanism	Flow Control Clamp	Flow Control Valve	Same as K234083
Aspiration Pump	• Capable of achieving pressure between -20 inHg to -29.9 inHg • Airflow rating of 0 – 23 LPM • IEC 60601-1 Compliant	• Capable of achieving pressure between -20 inHg and -25.6 inHg • Airflow rating ≥ 16 LPM	Same as K234083

Performance Testing Summary:

Biocompatibility:

Biological safety evaluation was conducted for the Raptor Aspiration Catheter 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 September 2023.

Additionally, the risk management process determined that the biocompatibility testing conducted on the reference device Next Generation Aspiration Catheter (K234083) and the Next Generation 6F+ Access Sheath (K242376), per ISO 10993-1 and applicable regulatory requirements, adequately assesses the biocompatibility profile of the subject Raptor Aspiration Catheters for endpoints recommended by the FDA biocompatibility guidance for an externally communicating device with limited (≤24 hours) duration of contact with circulating blood. Additionally, a comparative assessment of the Raptor Aspiration Catheter, Next Generation Aspiration Catheter, and Next Generation 6F+ Access Sheath did not identify any significant differences in the surface characteristics or geometry of these devices:

Test	Test Method Summary	Results
Hemocompatibility – Comparative Surface Assessment	The test article and the comparison article(s) were visually inspected at a minimum 40x magnification.	Requirements have been met by the test article.

The Balt Aspiration Tubing Set and Introducer Sheath are identical in materials and manufacturing to those cleared as part of the Next Generation Aspiration Catheter and Balt Aspiration Tubing Set (K234083) and the Ballast 088 Long Sheath (K182918), respectively.

Performance Data – Bench:

The following performance bench testing was conducted for the Raptor Aspiration Catheter:

Test	Test Method Summary	Results
Dimensional Verification	The catheter outer diameter, inner diameter, usable length, tip length, and coating length were measured.	Pass
Surface Contamination	Visual inspection completed for surface defects.	Pass
Tensile Strength	The 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
Liquid Leakage	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	Testing verified the device can withstand internal liquid pressure under dynamic flow conditions with the distal end open.	Pass
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 and compared to the predicate.	Pass
Particulate Matter	The catheter underwent simulated use testing and particulate testing was conducted including a reference device for comparison.	Pass, comparable to predicate device
Hub Testing	The device shall meet the established acceptance criteria per ISO 80369-7.	Pass

Test	Test Method Summary	Results
Corrosion	Corrosion tested per ISO 10555-1.	No evidence of corrosion and met requirements per ISO 10555-1.
Coating Integrity	The coating integrity was inspected before and after preconditioning through 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.
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. Static burst pressures were compared to pressures of manual syringe delivery of worst-case fluids through the catheter.	The static burst values met the acceptance criterion.
Tip Buckling	The maximum force to cause catheter tip buckling while constrained at varying distances was measured.	The tip stiffness was similar to the predicate and reference device.
Radiopacity (Visibility)	The device was tested to demonstrate acceptable radiopacity.	Marker radiopacity is comparable to the predicate.
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, and trackability were similar to the predicate.
Clot Retrieval	The subject and predicate devices were prepared in accordance with their respective instructions for use and tested for clot retrieval in a clinically relevant anatomical model.	Clot retrieval was comparable to the predicate.
Lumen Collapse	Tested to verify that the catheter lumen does not collapse at maximum vacuum pressure for a duration of 6 minutes.	Pass
Vacuum Pressure	Tested to verify the vacuum pressure at the aspiration pump and distal tip of the catheter.	Pass

The following performance bench testing was conducted for the Balt Aspiration Tubing Set:

Test	Test Method Summary	Results
Dimensional Verification	The total length, inner diameter, and outer diameter were measured.	Pass
Surface Contamination	Surface contamination testing was performed in alignment with ISO 10555-1.	Pass
Lumen Collapse	Tested to verify that the aspiration tubing lumen does not collapse at maximum vacuum pressure for a duration of 6 minutes.	Pass

Test	Test Method Summary	Results
Tensile Strength	Testing was adopted from ISO 10555-1.	Pass
Tubing to Pump	The tubing to pump pressure was measured.	Pass
On/Off Functionality	The On/Off functionality of the tubing set was measured.	Pass
Tubing Hub Compatibility	The tubing hub compatibility was evaluated.	Pass

Sterilization and Shelf Life:
The Raptor Aspiration Catheter and Balt Aspiration Tubing Set are sterilized using an ethylene oxide sterilization cycle that was verified to a sterility assurance level of 1×10^{-6} in accordance with ISO 11135. Accelerated aging testing for the Raptor Aspiration Catheter and Balt Aspiration Tubing Set based on ASTM F1980 have established that the subject device and packaging remain functional for the labeled expiration date. Aging studies for packaging integrity, seal strength, and device functionality were performed and met the acceptance criteria.

Performance Data – Animal:
A determination of substantial equivalence is based upon successful completion of non-clinical bench testing.

Performance Data – Clinical:
A determination of substantial equivalence is based upon successful completion of non-clinical bench testing.

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