December 30, 2024

Balt USA, LLC
Alicia Smith
Senior Regulatory Affairs Specialist
29 Parker
Irvine, California 92618

Re: K242376
Trade/Device Name: Next Generation Access Platform
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: November 27, 2024
Received: November 29, 2024

Dear Alicia Smith:

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)*
K242376

Device Name
Next Generation Access Platform

Indications for Use *(Describe)*
The Next Generation Access Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary: K242376

Applicant:	Balt USA, LLC 29 Parker Irvine, CA 92618 Registration No.: 3014162263
Contact Person:	Alicia Smith Senior Specialist, Regulatory Affairs Email: alicia.smith@baltgroup.com

Date Summary Prepared:	November 27, 2024
Trade Name:	Next Generation Access Platform
Common Name:	Catheter, Percutaneous
Review Panel:	Neurology, Cardiovascular
Product Codes:	QJP, DQY
Regulation Number:	21 CFR 870.1250
Device Classification:	Class II
Predicate Devices:	Ballast 088 Long Sheath (K182918) Base Camp Sheath System (K191717)

Device Description:
The Next Generation Access Platform consists of the Next Generation Access Sheath, Dilator, Introducer Sheath, Rotating Hemostasis Valve (RHV), and Hemostasis Valve Adapter (HVA). The Next Generation Access Sheath is a single lumen, braid-reinforced, variable stiffness sheath with a radiopaque zone on the distal end and a luer hub on the proximal end. The Next Generation Access Sheath is compatible with introducer sheaths appropriately sized for the outer diameter of the Next Generation Access Sheath.

The Next Generation Access Platform is provided sterile, non-pyrogenic, and is intended for single use only.

The Dilator facilitates the percutaneous entry of the Next Generation Access Sheath by forming an atraumatic transition of the Next Generation Access Sheath through the skin and subcutaneous tissue to the vessel. The distal 40 cm portion of the Next Generation Access Sheath is covered with a hydrophilic coating to aid in reducing friction.

Indications for Use:
The Next Generation Access Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Comparison of Subject and Predicate Devices:

	Predicate Devices		**Subject Device**			
	Ballast 088 Long Sheath (K182918)	**Base Camp Sheath System (K191717)**	**Next Generation Access Platform (K242376)**			
Indications for Use	The Ballast 088 Long Sheath is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The Route 92 Medical Sheath System is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.	The Next Generation Access Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.			
Device Classification Product Code	Class II DQY (Percutaneous Catheter)	Class II DQY (Percutaneous Catheter)	Class II QJP (Percutaneous Catheter, Neurovasculature) DQY (Percutaneous Catheter)			
Dimensional Specifications						
	Ballast 088 Long Sheath	Base Camp Sheath System	Next Generation 6F+ Access Sheath		Next Generation 7F Access Sheath	
			Sheath	Dilator	Sheath	Dilator
Sheath Tip Shape	Straight	Straight	Same as K182918	Same as K182918	Same as K191717	Same as K191717
Overall Length	80 cm – 105 cm	90 cm	80 cm – 110 cm	95 cm – 120 cm	80 cm – 90 cm	95 cm -105 cm
Outer Diameter	8F or 0.106”	0.122”	0.108” (2.74 mm)	0.088”	0.120” (3.05 mm)	0.094”
Inner Diameter	0.088”	0.106”	0.091” (2.31 mm)	0.042”	0.099” (2.51 mm)	0.042”
Length from Radiopaque marker band to distal tip	0.025” (0.64 mm)		0.028” (0.70 mm)	N/A	0.028” (0.70 mm)	N/A
Device Attributes						
Catheter Materials	Commonly used medical grade plastics & stainless steel	Commonly used medical grade plastics & stainless steel	Same as K182918		Same as K191717	
Coating	Hydrophilic	Hydrophilic	Same as K182918		Same as K191717	
Packaging Materials	Commonly used medical device packaging materials	Commonly used medical device packaging materials	Same as K182918		Same as K191717	

Accessories	Dilator, Introducer Sheath, Rotating Hemostasis Valve, Hemostasis Valve Adapter	Dilator, Rotating Hemostasis Valve	Same as K182918	Dilator, Introducer Sheath, Rotating Hemostasis Valve, Hemostasis Valve Adapter
Sterilization				
How Supplied	Sterile, Single Use	Sterile, Single Use	Same as K182918	Same as K191717
Method	Ethylene Oxide	Ethylene Oxide	Same as K182918	Same as K191717

Biocompatibility:

The following biocompatibility testing was conducted for the Next Generation Access Sheath and Dilator. The Introducer Sheath, Rotating Hemostasis Valve, and Hemostasis Valve Adapter are identical in materials and manufacturing to those previously cleared in K182918.

Test	Test Method Summary	Results
Cytotoxicity – MEM Elution	Tested in accordance with ISO 10993-5.	The test article is considered non-cytotoxic.
Hemocompatibility – Hemolysis (Direct Contact & Extract Method)	Tested in accordance with ISO 10993-4.	The test article is considered non-hemolytic.
Hemocompatibility – Complement Activation SC5b-9 Assay	Tested in accordance with ISO 10993-4.	The test article performed similarly to the predicate comparator.
Hemocompatibility – Comparative Surface Assessment	The test article and predicate comparator were visually inspected at minimum 40x magnification.	Requirements have been met by the test article.
Hemocompatibility – *In Vitro* Blood Loop Assay (Next Generation Access Sheath)	Tested in accordance with ISO 10993-4.	The test article performed similarly to the comparator.
Hemocompatibility – *In Vitro* Blood Loop Assay (Dilator)	Tested in accordance with ISO 10993-4.	Requirements have been met by the test article.
Pyrogenicity – Material-Mediated Rabbit Pyrogen	Tested in accordance with <USP 151>.	Requirements have been met by the test article.
Sensitization – Guinea Pig Maximization Test	Tested in accordance with ISO 10993-10.	The test article did not elicit a sensitization response.
Systemic Toxicity – Acute Systemic Injection	Tested in accordance with ISO 10993-11.	Requirements have been met by the test article.
Irritation – Intracutaneous Reactivity	Tested in accordance with ISO 10993-23.	Requirements have been met by the test article.

Performance Data - Bench:
The following performance bench testing was conducted to assess the performance of the Next Generation Access Platform:

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	Tested to verify 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
Hub Validation Testing	The device shall meet the established acceptance criteria per ISO 80369-7.	Pass
Particulate Matter	The catheter underwent simulated use testing and particulate testing was conducted including a reference device for comparison.	Particulate generation was comparable to the predicate device.
Tip Buckling	The maximum force to cause catheter tip buckling while constrained at varying distances was measured.	The tip stiffness was comparable to the predicate and other cleared catheters.
Catheter Shaft Stiffness	Stiffness of catheter shaft measured along the length of the shaft.	Catheter shaft stiffness was comparable to the predicate device.
Corrosion	Corrosion tested per ISO 10555-1.	No evidence of corrosion and met requirements per ISO 10555-1.
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

Test	Test Method Summary	Results
Coating Integrity	The coating integrity was inspected before and after preconditioning through a simulated use model.	No evidence of surface damage or coating defects.
Saline and Contrast 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 (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, trackability, and retrieval were comparable to the predicate.

Sterilization and Shelf Life:
The Next Generation Access Platform is 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 Next Generation Access Platform based on ASTM F1980 has 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:
No animal study was conducted because bench performance testing was deemed sufficient for verification and validation and to support substantial equivalence.

Performance Data – Clinical:
No clinical study was conducted because bench performance testing was deemed sufficient for verification and validation and to support substantial equivalence.

Conclusion:
The evidence presented in this 510(k) submission demonstrates substantial equivalence between the subject device and the predicate devices. The subject and predicate devices have the same intended use and indications for use. The differences in technological characteristics do not raise new questions of safety or effectiveness. Nonclinical bench, biocompatibility, and shelf-life testing demonstrates the Next Generation Access Platform meets the device specifications and performs as intended.