



July 2, 2024

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

Re: K234074  
Trade/Device Name: Next Generation Access Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: QJP, DQY  
Dated: May 31, 2024  
Received: June 3, 2024

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.

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](mailto: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

## Indications for Use

Submission Number (if known)

K234074

Device Name

Next Generation Access Catheter

Indications for Use (Describe)

The Next Generation Access Catheter 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: K234074**

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

<b>Date Summary Prepared:</b>	June 28, 2024
<b>Trade Name:</b>	Next Generation Access Catheter
<b>Common Name:</b>	Catheter, Percutaneous
<b>Review Panel:</b>	Neurology, Cardiovascular
<b>Product Code:</b>	QJP, DQY
<b>Regulation Number:</b>	21 CFR 870.1250
<b>Device Classification:</b>	Class II
<b>Predicate Device:</b>	BENCHMARK BMX81 Access System 510(k) #: K221822

**Device Description:**

The Next Generation Access Catheter is a single-lumen, flexible, variable stiffness composite catheter. The distal tip of the catheter shaft includes a marker band while the proximal end of the catheter has a luer fitting to allow attachment of accessories and infusion of liquids through the system. The Next Generation Access Catheter distal shaft has an external hydrophilic coating which provides a lubricious surface during use. The Next Generation Access Catheter is visible under fluoroscopy. The Next Generation Access Catheter dimensions are included on the individual device label. The Next Generation Access Catheter is offered in various sizes to accommodate physician preferences and anatomical variations.

A peelable split introducer sheath is provided in the package to provide support and facilitate the introduction of the distal tip of the Next Generation Access Catheter into an appropriate vascular sheath.

The catheter and introducer sheath are provided sterile, non-pyrogenic, and are intended for single use only.

**Indications for Use:**

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

Comparison of Technological Characteristics:

	<b>Predicate Device</b>	<b>Subject Device</b>
	<b>BENCHMARK BMX81 Access System (K221822)</b>	<b>Next Generation Access Catheter (K234074)</b>
Indications for Use	The BENCHMARK BMX81 Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The Next Generation Access Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Device Classification / Product Code	Class II / QJP, DQY (Percutaneous Catheter)	Same as K221822
<b>Dimensional Specifications</b>		
Catheter Outer Diameter (OD)	7F (2.46 mm, 0.097")	6.F (2.11 mm, 0.083") – 7F (2.36 mm, 0.093")
Catheter Inner Diameter (ID)	0.081" (2.06 mm)	0.071" – 0.081" (1.80 mm – 2.06 mm)
Effective Length	95 cm, 105 cm, 115 cm	110 cm – 132 cm
Coating Length	18 cm	60 cm
<b>Device Attributes</b>		
Catheter Materials	Commonly used medical grade plastics & stainless steel	Same as K221822
Coating	Hydrophilic	Same as K221822
Packaging Materials	Commonly used medical device packaging materials	Same as K221822
<b>Sterilization</b>		
How Supplied	Sterile, Single Use	Same as K221822
Method	Ethylene Oxide	Same as K221822

Performance Testing Summary:

Biocompatibility:

The following biocompatibility testing was conducted for the Next Generation Access Catheter:

<b>Test</b>	<b>Test Method Summary</b>	<b>Results</b>
Cytotoxicity – MEM Elution	Tested in accordance with ISO 10993-5	<b>Pass</b> The test article is considered non-cytotoxic.
Hemocompatibility – Hemolysis (Direct Contact & Extract Method)	Tested in accordance with ISO 10993-4	<b>Pass</b> The test article is considered non-hemolytic.
Hemocompatibility – Complement Activation SC5b-9 Assay	Tested in accordance with ISO 10993-4	<b>Pass</b> Requirements have been met by the test article.
Hemocompatibility – Partial Thromboplastin Time (PTT)	Tested in accordance with ASTM F2382-18	<b>Pass</b> Requirements have been met by the test article.
Hemocompatibility – Blood Platelet and Leukocyte Count (PLC)	Tested in accordance with ASTM F2888-19	<b>Pass</b> Requirements have been met by the test article.
Hemocompatibility – Comparative Surface Assessment	The test article was visually inspected at more than 40x magnification.	<b>Pass</b> Requirements have been met by the test article.
Hemocompatibility – Thrombogenicity in a Canine Model	Tested in accordance with ISO 10993-4	<b>Pass</b> The test article performed similarly to the comparator.
Pyrogenicity – Material-Mediated Rabbit Pyrogen	Tested in accordance with <USP 151>	<b>Pass</b> Requirements have been met by the test article.
Sensitization – Guinea Pig Maximization Sensitization	Tested in accordance with ISO 10993-10	<b>Pass</b> The test article did not elicit a sensitization response.
Systemic Toxicity – Acute Systemic Injection	Tested in accordance with ISO 10993-11	<b>Pass</b> Requirements have been met by the test article.
Irritation – Intracutaneous Reactivity	Tested in accordance with ISO 10993-23	<b>Pass</b> 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 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	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.	Pass
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.
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 Catheters are sterilized using an ethylene oxide sterilization cycle that was verified to a sterility assurance level of  $1 \times 10^{-6}$  in accordance with ISO 11135. Accelerated aging testing for the Next Generation Access Catheter 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 device. 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 and effectiveness. Nonclinical bench testing demonstrates the Next Generation Access Catheter meets the device specifications and perform as intended.