



April 16, 2026

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

Re: K254223
Trade/Device Name: Next Generation 088 Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: December 26, 2025
Received: December 29, 2025

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,


JAIME RABEN -S

for 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

510(k) Number (if known)
K254223

Device Name
Next Generation 088 Catheter

Indications for Use (Describe)

The Next Generation 088 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.

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510(k) Summary: K254223

Applicant:	Balt USA, LLC 29 Parker Irvine, CA 92618 Registration No.: 3014162263
Contact Person:	Subha Elango Manager, Regulatory Affairs Telephone: (949) 788-1443 Email: subha.elango@baltgroup.com

Date Summary Prepared:	April 15, 2026
Trade Name:	Next Generation 088 Catheter
Common Name:	Catheter, Percutaneous
Review Panel:	Neurology, Cardiovascular
Product Code:	QJP, DQY
Regulation Number:	21 CFR 870.1250
Regulation Name:	Percutaneous Catheter
Device Classification:	Class II
Predicate Device:	Next Generation Access Catheter 510(k) #: K234074
Reference Device(s):	Sofia 88 Catheter 510(k) #: K214024

Device Description:

The Next Generation 088 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 088 Catheter distal shaft has an external hydrophilic coating which provides a lubricious surface during use.

The Next Generation 088 Catheter is visible under fluoroscopy. The Next Generation 088 Catheter dimensions are included on the individual device label. The Next Generation 088 Catheter is offered in various lengths to accommodate physician preferences and anatomical variations. The catheter, dilator, introducer sheath and accessories are provided sterile, non-pyrogenic, and are intended for single use only.

Indications for Use:

The Next Generation 088 Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Comparison of Technological Characteristics:

	Predicate Device	Reference Device	Subject Device
	Next Generation Access Catheter (K234074)	Sofia 88 Catheter (K214024)	Next Generation 088 Catheter (K254223)
FDA Product Classification	Class II, QJP, DQY, 21 CFR 870.1250	Same as K234074	Same as K234074
Indications for Use	The Next Generation Access Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	Same as K234074	Same as K234074
Dimensions – Catheter			
Effective Length	110 cm – 132 cm	115 cm	110 – 115 cm
Outer Diameter	0.093 in (2.36 mm)	Proximal: 0.108 in (2.74 mm) max Distal: 0.102 in (2.59 mm) max	0.110 in (2.79 mm)
Inner Diameter	0.081 in (2.06 mm)	0.0875 in (2.2 mm)	0.088 in (2.24 mm)
Coating	Hydrophilic coating	Same as K234074	Same as K234074
Tip Configuration	Straight	Same as K234074	Same as K234074
Dimensions – Dilator			
Working Length	N/A	N/A	126 – 131 cm
Outer Diameter	N/A	N/A	Proximal: 0.084” (2.13 mm) Distal: 0.040” (1.02 mm)
Inner Diameter	N/A	N/A	0.038” (0.96 mm)
Materials			
Catheter Materials	Commonly used medical grade plastics & stainless steel	Outer layer of polyurethane elastomer (different polyurethane formulation), polyether block amide, and polyamide; inner layer of metal braid/coil, PTFE, and polyolefin elastomer	Same as K234074
Packaging	HDPE dispenser tube, polyethylene packaging card, Tyvek pouch. Pouch, bleached sulfate carton box.	Same as K234074	Same as K234074

	Predicate Device	Reference Device	Subject Device
	Next Generation Access Catheter (K234074)	Sofia 88 Catheter (K214024)	Next Generation 088 Catheter (K254223)
Sterilization			
Method	Ethylene Oxide	Same as K234074	Same as K234074
How Supplied	Sterile, Single Use	Same as K234074	Same as K234074
Accessories			
Accessories supplied with device	Introducer sheath	Same as K234074	Dilator, introducer sheath, 9F Rotating Hemostasis Valve, and 8F Hemostasis Valve Adaptor

Biocompatibility

Biological safety evaluation was conducted for Next Generation 088 Catheter and accessories 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 predicate device Next Generation Access Catheter (K234074) and the Next Generation 6F+ Access Sheath (K242376), per ISO 10993-1 and applicable regulatory requirements, adequately assesses the biocompatibility profile of the subject device, Next Generation 088 Catheter, 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 Next Generation 088 Catheter, Next Generation Access 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	Results
Hemocompatibility – Comparative Surface Assessment	The test article and the comparison article(s) were visually inspected at a minimum 40x magnification.	Subject device similar to the comparison article.

Performance Testing – Bench

The following performance bench tests were conducted to assess the performance of the Next Generation 088 Catheter.

Test	Acceptance Criteria	Results
Dimensional Verification	Verify that the device meets dimensional requirements	Pass
Surface Contamination	Visual inspection completed 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
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
Turns to Failure (Torque Strength)	The device was evaluated for torque strength by measuring the	Pass

Test	Acceptance Criteria	Results
	number of catheter rotations until failure after preconditioning in a simulated use model and compared to the predicate.	
Hub Verification	The device shall meet the functional requirements 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 Resistance	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
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	Verify that radiopaque markers are visible using standard fluoroscopic equipment.	Pass
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 088 Catheter 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 Testing – Animal:

No animal study was conducted because bench performance testing was deemed sufficient for verification and validation and to support substantial equivalence.

Performance Testing – 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 difference in technological characteristics does not raise new questions of safety or effectiveness. Nonclinical bench, biocompatibility, and shelf-life testing demonstrate the Next Generation 088 Catheter meets the device specifications and performs as intended.