



October 22, 2025

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

Re: K252569

Trade/Device Name: Carrier XL Delivery Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: QJP, DQY  
Dated: September 19, 2025  
Received: September 22, 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](mailto: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

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)  
K252569

Device Name  
Carrier XL Delivery Catheter

Indications for Use (Describe)

The Carrier XL Delivery Catheter is intended for general intravascular use, including the peripheral, coronary and neurovasculature 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.

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: K252569**

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

<b>Date Summary Prepared:</b>	October 17, 2025
<b>Trade Name:</b>	Carrier XL Delivery Catheter
<b>Common Name:</b>	Catheter, Percutaneous
<b>Review Panel:</b>	Neurology
<b>Product Code:</b>	QJP, DQY
<b>Regulation Number:</b>	21 CFR 870.1250
<b>Regulation Name:</b>	Percutaneous Catheter
<b>Device Classification:</b>	Class II
<b>Predicate Device:</b>	NG Delivery Catheter 510(k) #: K230609

**Device Description:**

The Carrier XL Delivery Catheter is a single lumen, variable stiffness, composite catheter. The design facilitates the advancement of the catheter and is intended to assist the delivery of interventional devices in the peripheral and neurovasculature. The outer surface of the Carrier XL Delivery Catheter is coated with a hydrophilic coating to increase lubricity. The proximal end of the Carrier XL Delivery Catheter incorporates a luer fitting for the attachment of accessories. Two radiopaque markers at the distal end help to facilitate fluoroscopic visualization. A Steam Shaping Mandrel and Peel-away Introducer Tube are included within the tray. The Carrier XL Delivery Catheter is provided sterile, non-pyrogenic, and is intended for single use only.

**Indications for Use:**

The Carrier XL 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.



**Comparison of Technological Characteristics:**

<b>Design Attribute / Components</b>	<b>Predicate Device: NG Delivery Catheter (K230609)</b>	<b>Subject Device: Carrier XL Delivery Catheter (K252569)</b>
Device Classification / Product Code	Class II / QJP, DQY (Percutaneous Catheter)	Same as K230609
Indications for Use	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 Carrier XL 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.
Catheter OD, Max	0.069" (1.75 mm)	0.077" (1.96 mm)
Catheter ID	0.021" (0.53 mm)	Same as K230609
Usable Length	152 cm	142 cm 152 cm 162 cm
Coating Length	60 cm	Same as K230609
Coating	Hydrophilic	Same as K230609
<b>Packaging Configuration</b>		
Configuration	Catheter is placed in a dispenser hoop, then inserted into a pouch and placed inside a carton box	Same as K230609
<b>Sterilization</b>		
Sterilization Method	Ethylene Oxide	Same as K230609
Supply Method	Sterile, Single Use	Same as K230609



Performance Testing Summary:

Biocompatibility:

The subject device is classified as an externally communicating device with circulating blood contact for a limited duration ( $\leq 24$  hours) in accordance with ISO 10993-1 and the FDA guidance document, “Use of International Standard ISO 10993-1, “Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process.” The design and manufacturing of the subject device utilize the same materials, processing methods, and sterilization as the predicate device (K230609), for which Balt has already conducted biocompatibility testing in compliance with ISO 10993-1. Therefore, no additional biocompatibility testing is required.

Performance Data – Bench:

The following performance bench testing was conducted for the Carrier XL Delivery Catheter:

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, and trackability were similar to the predicate.
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 device.
Dimensional Verification	The dimensional attributes impacted by the change were measured.	The dimensional specifications were met.
Kink Resistance	Kink resistance was evaluated by wrapping the catheter around bends with clinically relevant radii.	Subject device meets the same criteria as the predicate device.
Flow Rate	The flow rate of contrast media and saline and associated injection pressures were evaluated.	The flow rate was characterized.

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 identical intended use, similar technological characteristics, and the results of the non-clinical testing, the Carrier XL Delivery Catheter is found to be substantially equivalent to the predicate device (K230609). The differences in technological characteristics do not raise new questions of safety and effectiveness. Testing was conducted to demonstrate that the subject device, Carrier XL Delivery Catheter, meets the specifications and performs as intended.