September 13, 2023

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

Re: K230609
Trade/Device Name: NG Delivery Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: August 17, 2023
Received: August 17, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K230609

Device Name
NG Delivery Catheter

Indications for Use *(Describe)*
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.

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: K230609**

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

| | |
|---|---|
| **Date Summary Prepared:** | September 13, 2023 |
| **Trade Name:** | NG Delivery Catheter |
| **Common Name:** | Catheter, Percutaneous |
| **Review Panel:** | Neurology |
| **Product Code:** | QJP, DQY |
| **Regulation Number:** | 21 CFR 870.1250 |
| **Device Classification:** | Class II |
| **Predicate Device:** | Wedge Microcatheter<br>510(k) #: K172014 |
| **Reference Device:** | AXS Offset Delivery Assist Catheter<br>510(k) #: K163259 |

**Device Description:**

The NG 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 NG Delivery Catheter is coated with a hydrophilic coating to increase lubricity. The proximal end of the NG 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 NG Delivery Catheter is provided sterile, non-pyrogenic, and is intended for single use only.

**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.

**Device Comparison:**

| | Predicate Device: Wedge Microcatheter (K172014) | Reference Device: AXS Offset Delivery Assist Catheter (K163259) | Subject Device: NG Delivery Catheter (K230609) |
|---|---|---|---|
| Device Classification / Product Code | Class II/DQY (Percutaneous Catheters) | Same as K172014 | Class II/QJP, DQY (Percutaneous Catheters) |
| Indications for Use | The Wedge Microcatheter 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 the SOFIA 6F Catheter, in the neurovasculature. | The AXS Offset Delivery Assist Catheter is intended to assist in the delivery of interventional devices, such as distal access catheters, in the neurovasculature. | 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. |
| Catheter OD, Max | 1.73 mm (0.068") | 3.8F (1.27 mm; 0.05") | 4.5F (1.50 mm; 0.059") – 5.3F (1.75 mm; 0.069") |
| Catheter ID | 0.53 mm (0.021") | 0.53 mm (0.021") | Same as K172014 |
| Effective Length | 158 cm – 160 cm | 150 cm | 152 cm |
| Coating Length | 110 cm – 115 cm | 80 cm | 60 cm |
| Packaging Configuration | | | |
| Configuration | Microcatheter is placed in a dispenser hoop and accessories on a mounting card that is then inserted into the pouch. The pouch is then placed inside a carton box. | Catheter is placed in a dispenser coil, then inserted into a pouch and placed inside a carton box. | Same as K172014 |
| Sterilization | | | |
| Method | Ethylene Oxide | Same as K172014 | Same as K172014 |
| How Supplied | Sterile, Single Use | Same as K172014 | Same as K172014 |

**Biocompatibility:**
The following biocompatibility testing was conducted for the subject device, NG Delivery Catheter:

| Test | Results | Conclusions |
|---|---|---|
| Cytotoxicity (ISO MEM Elution Test) | The test article scored a '1' and is considered non-cytotoxic under the conditions of the test. | The test article is considered non-cytotoxic. |
| Sensitization (ISO Guinea Pig Maximization Test) | None of the test animals challenged with the test article extracts were observed with a sensitization response greater than '0'. | The test article did not elicit a sensitization response. |
| Intracutaneous Reactivity | The differences in the mean test and control scores of the extract dermal observations were 1.0 or less. | Requirements have been met by the test article. |
| Acute Systemic Toxicity | None of the animals in the study were observed with abnormal clinical signs indicative of toxicity during the 72-hour test period. All were alive at the end of the 72-hour test duration and body weight changes were within acceptable parameters over the course of the study. | Requirements have been met by the test article. |
| Material-Mediated Pyrogenicity (ISO Materials Mediated Rabbit Pyrogen) | None of the rabbits administered with the test article extract had a temperature rise $\geq 0.5°C$ at the required observation time points. | The test article is considered non-pyrogenic. |
| Hemocompatibility – Hemolysis | The test article, in both extract and direct method, met the criteria for assay validity and displayed an Average Blank Corrected Hemolytic Index above the Negative Control below 2.0%. | The test article is considered non-hemolytic. |
| Hemocompatibility – Complement Activation | The test article result was statistically significantly lower ($p<0.05$) than that of the comparison article. | Test article performed better than the comparison article under the conditions employed. |
| Hemocompatibility – Thrombogenicity (In vivo) | The test article has "normal" vessel observations, and patency of "not occluded" for both left/right external jugulars. | Scores indicate low thrombogenic potential for the test device. |
| Hemocompatibility – Thrombogenicity (Partial Thromboplastin Time) | The clotting time of the test article and the comparison article are not significantly different. | Requirements have been met by the test article. |
| Hemocompatibility – Thrombogenicity (Platelet Leukocyte Count) | The test article platelet mean percentage value was between 80 to 120% and was at least 30% above the positive control. | Requirements have been met by the test article. |
| Hemocompatibility – Thrombogenicity (Comparative Surface Assessment) | Each device was inspected with zero noted locations with rough surfaces or defects. | Requirements have been met by the test article. |

**Performance Data - Bench:**

The following non-clinical bench testing was conducted to assess the performance of the subject device, NG Delivery Catheter:

| Test | Test Method Summary | Results |
|---|---|---|
| Physical and Dimensional | The physical and dimensional attributes were measured. | All samples passed the acceptance criteria. |
| Tensile Strength | The peak tensile force was obtained per ISO 10555-1. | All samples passed the acceptance criteria. |
| Kink Resistance | Kink resistance was evaluated after subjecting the device to bending in a simulated use model. | All samples passed the acceptance criteria. |
| Liquid-Leakage | The device was exposed to a minimum liquid pressure for a minimum of 30 seconds. The device was inspected for leakage per ISO 10555-1. | All samples passed the acceptance criteria. |
| Air Leakage | The device was exposed to air pressure by syringe. The device was inspected for leakage per ISO 10555-1. | All samples passed the acceptance criteria. |
| Static Burst | The distal tip of the catheter was blocked, and fluid was injected into the lumen at increasing pressure until the catheter burst. | All samples passed the acceptance criteria. |
| Torque Strength | The device was evaluated for torque strength by measuring the number of catheter rotations until failure after tracking through a simulated use model. | All samples passed the acceptance criteria. |
| Catheter Tip Shapeability | Tip shapeability of the distal tip was measured after steam shaping. | All samples passed the acceptance criteria. |
| Hub Validation Testing | The luer connector was tested to functional requirements per ISO 80369-7 and non-interconnectability to other hubs per ISO 80369-1. | All samples passed the acceptance criteria. |
| Coating Adherence | The coating integrity was inspected under simulated use conditions. | All samples passed the acceptance criteria. |
| Particulate Matter | The catheter underwent simulated use testing and particulate testing was conducted including a reference device for comparison. | All samples passed the acceptance criteria. |
| Tip Stiffness | The catheter stiffness profile was compared to the reference device. | The tip stiffness was comparable. |
| Flow Rate | The flow rate of contrast media and associated injection pressures were evaluated. | Characterization only |

| Test | Test Method Summary | Results |
|---|---|---|
| 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. | All samples passed the acceptance criteria. |
| Lubricity (Friction Force) | The lubricity peak friction force was measured. | Characterization only |
| Radiopacity (Visibility) | The device was tested to demonstrate acceptable radiopacity. | Acceptable |
| Physician Usability | The devices were prepared in accordance with their respective instructions for use and met established acceptance criteria for device usability in a clinically relevant anatomical model. | All samples passed the acceptance criteria. |

**Performance Data – Animal:**
Balt USA, LLC did not conduct non-clinical animal testing. The differences in technological characteristics do not raise new questions of safety and effectiveness.

**Performance Data – Clinical:**
Balt USA, LLC did not conduct clinical testing. The differences in technological characteristics do not raise new questions of safety and effectiveness.

**Conclusion:**
The evidence presented in this 510(k) 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. Non-clinical bench testing demonstrates the NG Delivery Catheter meets the specifications.