March 21, 2019

Balt USA, LLC
Charles Yang
Senior Vice President, Quality Assurance and Regulatory Affairs
29 Parker
Irvine, California 92618

Re: K182918
Device Name: Ballast 088 Long Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 15, 2019
Received: February 19, 2019

Dear Charles Yang:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lin Zheng
Digitally signed by Xiaolin Zheng -S
Date: 2019.03.21 10:11:36 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182918

Device Name
Ballast 088 Long Sheath

Indications for Use *(Describe)*
The Ballast 088 Long Sheath 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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Ballast 088 Long Sheath
510(k) Summary

This 510(k) summary for Ballast 088 Long Sheath is submitted in accordance with the requirements of 21 CFR 807.87(h) and 807.92 and following the recommendation outlined in FDA Guidance, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)]*, dated 28 July, 2014.

SUBMITTER [807.92(a)(1)]

Balt USA, LLC
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Irvine CA 92618

Contact Person:	Charles Yang Senior Vice President, Quality Assurance and Regulatory Affairs
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Date prepared:	March 13, 2019

DEVICE [807.92(a)(2)]

Name of Device:	Ballast 088 Long Sheath
Common or Usual Name:	Guide Catheter / Long Sheath
Classification Name:	Catheter, Percutaneous
Product Code:	DQY
Regulatory Class:	Class II
Submission Type:	Traditional 510(k)
Regulation Number:	21 C.F.R. 870.1250
Reviewing Product Branch:	Division of Neurological and Physical Medicine Devices (Office of Device Evaluation, CDRH)

PREDICATE DEVICE [807.92(a)(3)]

Neuron MAX System (K111380)

DEVICE DESCRIPTION [807.92(a)(4)]

The Ballast 088 Long Sheath is a sterile, single use, single lumen, variable stiffness Guide Catheter / Long Sheath that is designed for facilitating the introduction of appropriately sized interventional devices into target blood vessels in the peripheral, coronary, and neuro vasculature.

The Ballast 088 Long Sheath consists of a lubricous inner liner made from Polytetrafluoroethylene (PTFE) reinforced by a stainless steel coil over the inner liner and stainless steel braid partially covering the inner coil layer. The outer jacket consists of thermoplastics ranging from thermoplastic polyurethane (TPU), polyether block amide (Pebax), and polyamide 12.

The distal section of the Ballast 088 Long Sheath is coated with hydrophilic coating to provide lubricity during use. A Platinum/Iridium marker band is placed at the distal end of the catheter for maximum radiopacity. An introducer sheath, 9F hemostasis valve, 8F hemostasis valve adapter and a dilator are also provided with the device.

INDICATIONS FOR USE [807.92(a)(5)]

The Ballast 088 Long Sheath is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS [807.92(a)(6)]

The technological characteristics of the Ballast 088 Long Sheath are highly analogous to the technological characteristics of the Neuron MAX™ System previously cleared (K111380). Substantial equivalence is determined based on the following similarities:

- Same intended use/indications for use
- Same principles of operation
- Same fundamental scientific technology
- Incorporate similar basic Guide Catheter / Long Sheath design
- Incorporate similar Guide Catheter / Long Sheath construction material

Table 1 comprises the comparison between Ballast 088 Long Sheath (Subject Device) and Neuron MAX™ System (Predicate Device, K111380).

Table 1: Predicate Device vs. Subject Device Comparison Table

Feature	Neuron MAX™ System [PREDICATE DEVICE K111380]	Ballast 088 Long Sheath [SUBJECT DEVICE]
Product Code	DQY	Same
Regulatory Class	Class II	Same
Regulation Number	21 CFR 870.1250	Same
Regulation Name	Catheter, Percutaneous	Same
Generic Name	Guide Catheter / Long Sheath	Same
Indications for Use Statement	The Neuron MAX™ System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	Same
Function	Guide Catheter / Long Sheath for facilitating the introduction of appropriately sized interventional devices into target blood vessels in the peripheral, coronary, and neuro vasculature	Same
Principle of Operation	The steerable Guide Catheter / Long Sheath is used to facilitate the selective placement of interventional devices	Same
Anatomical Location	Peripheral, coronary, and neuro vasculature.	Same
Visualization	Visible under radiographic imaging	Same

Feature	Neuron MAX™ System [PREDICATE DEVICE K111380]	Ballast 088 Long Sheath [SUBJECT DEVICE]
Configurations	PNML6F088804 (Usable Length 80, Straight Tip Shape) PNML6F088804M (Usable Length 80, Multipurpose Tip Shape) PNML6F088904 (Usable Length 90, Straight Tip Shape) PNML6F088904M (Usable Length 90, Multipurpose Tip Shape)	Ballast80 (Usable Length 80 cm) Ballast90 (Usable Length 90 cm) Ballast100 (Usable Length 100 cm) Ballast105 (Usable Length 105 cm)
Tip Shape	Straight, Multipurpose	Straight
Overall Length	80 cm – 90 cm	80 cm – 105cm
Proximal Outer Diameter	8F	Same
Distal Outer Diameter	8F	Same
Internal Diameter	0.088”	Same
Coil Length	Not Listed	77 cm – 102 cm
Length from Radiopaque marker band to distal tip	Not Listed	0.025”
Braided Shaft Length	Not Listed	9 cm from distal tip

Feature	Neuron MAX™ System [PREDICATE DEVICE K111380]	Ballast 088 Long Sheath [SUBJECT DEVICE]
Coil	Not Listed	Stainless Steel
Inner Liner	Not Listed	PTFE
Braid	Stainless Steel	Same
Radiopaque Marker	Not Listed	Platinum/Iridium
Coating	Hydrophilic Coating	Same
Hydrophilic Coating Length	Not Listed	20 cm
Method of supply	Sterile and single use	Same
Sterilization method	Ethylene oxide gas	Same
Accessories	Rotating Hemostasis Valve (RHV) Hemostasis valve adapter (HVA) Dilator	Introducer sheath 9F rotating hemostasis valve 8F hemostasis valve adapter Dilator
Package configuration	Placed into a packaging card, Tyvek pouch and Carton box.	Same

PERFORMANCE DATA [807.92(b)]

Performance Bench Testing and Animal Testing: Results of the performance bench testing and animal testing (**Table 2**) indicate that Ballast 088 Long Sheath (Subject Device) meets established performance requirements and is substantially equivalent for its intended use.

Table 2: Performance Bench Testing and Animal Testing Summary

Performance Bench Testing		
Tests	**Test Method Summary**	**Results**
Visual and Dimensional Inspection	Inspected dimensions for overall length, total length of proximal hub and strain relief, inner diameter, outer diameter (distal and proximal).	All test samples passed testing.
Surface Contamination	A microscope was used to inspect the catheter surface for the presence of particulates.	All test samples passed testing
Catheter Compatibility	Verify the compatibility of the Ballast 088 Long Sheath with the following: - Accessory devices - Guidewire - 6F dilator and guidewire - Inner guide catheter and guidewire - Inner diagnostic catheter and guidewire	All test samples passed testing.
Simulated Use	Verify the *in vitro* performance of the test article under simulated use conditions using Type III, Bovine Aortic Arch vessel model.	All test samples passed testing.
Coating Integrity and Adherence	Test samples were dyed and gone through simulated use testing. The coating quality	All test samples passed testing

	of the dyed test articles were inspected under a microscope.	
Lubricity/Durability of Hydrophilic Coating	Test samples underwent 25 friction cycles with a maximum friction force of 75 grams to determine the lubricity and durability of the catheter coating.	All test samples passed testing.
Dynamic Burst	A MEDRAD Mark V Plus Injection System was used to measure catheter dynamic burst test of the test samples.	All test samples passed testing.
Liquid Leakage at 46 psi	Determined whether liquid leaks from the catheter under a pressure of 46 psi per ISO 10555-1 and ISO 594-2.	All test samples passed testing.
Air Leakage	Determined whether air leaks into the hub assembly during aspiration per EN ISO 10555-1 and ISO 594-2.	All test samples passed testing.
Catheter Static Burst Test	A hydraulic Burst/Leak tester was used to test the static burst resistance of the test samples per ISO 10555-1.	All test samples passed testing.
Tensile Strength	Measured the catheter shaft peak tensile force and the hub to shaft peak tensile force using an Intron tensile tester per the guidelines in ISO 10555-1.	All test samples passed testing.
Corrosion Resistance	The test article is immersed in sodium chloride solution before being placed in boiling distilled or deionized water. Subsequently, the test article is examined visually for evidence of corrosion.	All test samples passed testing.
Torque Strength	Torque strength was determined by number of turns-to-failures. Torque strength of the subject device was compared to the predicate device.	All test samples passed testing. The Torque Strength of the subject device is comparable to the predicate device.

Kink Resistance Test	The kink resistance of the test samples was tested against the predicate device in simulated use. In addition, kink resistance of the test samples was tested against the predicate device by wrapping the device around a pin and examining the device for kinks by using a microscope.	All test samples passed testing. The Kink Resistance of the subject device is comparable to the predicate device.
Catheter Stiffness Testing	An Instron tensile tester was used to characterize the stiffness profile of the device.	All test samples passed testing.
Fracture Resistance and Flexing Test	Testing was conducted to determine the Guide Catheter's resistance to damage by flexing and resistance to fracture per ISO 11070.	All test samples passed testing.
Particulate Matter Characterization	Particulate matter in injections of the device were quantified after simulated use.	All test samples passed testing.
Luer Dimensional Inspection	Inspected the luer dimensions per ISO 80369-7.	All test samples passed testing.
Separation Force	Verified mating parts separation force per ISO 594-1 and ISO 594-2.	All test samples passed testing.
Unscrewing Torque	Verified that the catheter luer remained attached after applying an unscrewing torque, per ISO 594-1 and ISO 594-2.	All test samples passed testing.
Resistance to Overriding	Verified that the catheter luer did not override reference fitting threads, per ISO 594-1 and ISO 594-2.	All test samples passed testing.
Stress Cracking	Verified that there were no stress cracks on microcatheter hub, per ISO 594-1 and ISO 594-2.	All test samples passed testing.
Subatmospheric-pressure Air Leakage	ISO 80369-7	All test samples passed testing.

	The fittings were assembled by applying an axial force while rotating the test connector. The test connector and reference connector assembly were secured to the test port on the pressure decay leak tester and the pressure decay rates were recorded.	
Separation Force	ISO 80369-7 The fittings were assembled by applying an axial force while rotating the test connector. An axial force is applied in the direction away from the test connection.	All test samples passed testing.
Stress Cracking	ISO 80369-7 The fittings were assembled by applying an axial force while rotating the test connector. The test connector is disconnected from the reference connector and is reassembled again. With the axis of the lock fitting horizontal, the assembly outlet is sealed and the internal water pressure is brought to an effective pressure and maintained for a specific time.	All test samples passed testing.
Unscrewing Torque	ISO 80369-7 The fittings were assembled by applying an axial force while rotating the test connector. A screwing torque was applied for a certain hold period.	All test samples passed testing.
Resistance to Overriding	ISO 80369-7 The fittings were assembled by applying an axial force while rotating the test connector. Using a torque watch with no axial load, a torque is applied for a specific hold period.	All test samples passed testing.

Packaging Integrity Test		
Visual Inspection (Product carton)	Visually inspected packaging for any signs of damage.	All test samples passed testing.
Seal strength	Perform seal strength test per ASTM F88/F88M.	All test samples passed testing.
Bubble Immersion	Perform Bubble Immersion test per ASTM F2096-11. No bubbles observed attributable to leaks and no test fluid attributable to leaks inside the device packaging.	All test samples passed testing.
Visual Inspection (Seal Integrity)	Visual inspection testing was performed per ASTM F1886/F1886M-16 to visually detect channel defects in package seals.	All test samples passed testing.
Performance Animal Testing		
Animal Testing (GLP)	Animal testing is to evaluate the *in vivo* performance of the device in an acute porcine model. Trackability and handling of the guide catheter, radiopacity, and catheter compatibility were assessed. Subject device was compared to predicate device.	All test samples passed testing. Trackability and handling of the guide catheter, radiopacity, and catheter compatibility with microcatheter were comparable to predicate device.

Biocompatibility: Results of the biocompatibility testing (**Table 3**) indicate that the Ballast 088 Long Sheath (Subject Device) is biocompatible and is substantially equivalent for its intended use.

Table 3: Biocompatibility Test Summary

Test	Results	Conclusion
Cytotoxicity – MEM Elution Test – 48 hours ISO 10993-5	Test Article extract showed no evidence of lysed cells or cytotoxicity to L-929 cells, with an average grade of 0 (no reactivity).	Non-cytotoxic
Sensitization - ISO Guinea Pig Kligman Maximization Test ISO 10993-10	The 0.9% Sodium Chloride for injection (NaCl) and Cottonseed Oil (CSO) extracts did not induce delayed sensitization in the guinea pig (0% Sensitization).	Did not elicit sensitization response
Irritation or Intracutaneous – ISO Intracutaneous Study in Rabbits – Two Extracts ISO 10993-10	The difference between the test and the control mean score was 0.0.	Non-irritant
Acute Systemic Toxicity – ISO Acute Systemic Toxicity Study in Mice – Two Extracts ISO 10993-11	There was no evidence of significant systemic toxicity or mortality after test article extracts injection.	Non-toxic
Systemic Toxicity – ISO Materials Mediated Rabbit Pyrogen ISO 10993-11	During the 3-hour observation period, none of the rabbits administered with the test article extract had a temperature rise >0.5ºC at the required observation time points. This response did not exceed the USP limit and meets the requirements for this test. Therefore, these results indicate that the test article was determined to be non-pyrogenic.	Non-pyrogenic
Genotoxicity: Ames Test (Solids), 2 extracts, 4 strains of *Salmonella typhimurium* and one strain of *Escherichia coli* ISO 10993-3	The test article extracts did not produce a two-fold or a three-fold increase in the number of revertants in any of the 5 tester strains. The spot tests showed no zone of increased reversion or of toxicity. Therefore, the test article is considered non-mutagenic.	Non-mutagenic

Genotoxicity: Chromosomal Aberration Assay in Chinese Hamster Ovary (CHO) cells, 2 extracts, OECD 473 ISO 10993	The cytotoxicity data showed no reactivity to the test article solutions when placed on CHO cells. The polyploid, endoreduplication rate, and the mitotic index of the test article solutions showed no significant difference from the controls. Therefore, the test article is not considered to be genotoxic when exposed to CHO cells.	Non-genotoxic
Hemocompatibility-Hemolysis, ASTM Method (Indirect) ISO 10993-4	The difference between the hemolytic indexes of the test article and the negative control equals 0.15%, placing the test article in the non-hemolytic range according to the Hemolytic Grade scale	Non-Hemolytic
Hemocompatibility-Hemolysis, ASTM Method (Direct) ISO 10993-4	The difference between the hemolytic indexes of the test article and the negative control equals 0.00%, placing the test article in the non-hemolytic range according to the Hemolytic Grade scale	Non-Hemolytic
Hemocompatibility – Complement Activation, SC5b-9 ISO 10993-4	The results of the complement activation testing performed on the test article indicate that it has a complement activation comparable to the predicate device.	Passed
Hemocompatibility – Partial Thromboplastin Time (PTT) ISO 10993-4	The clotting times exhibited by the test article were lengthened when compared to the clotting times exhibited by the predicate device.	Passed
Hemocompatibility – Platelet and Leukocyte Count (PLC) ISO 10993-4	The triplicate test article replicates were within 25% of their average. The test article results for the leukocyte and platelet counts were 86.9% and 117.7%, respectively, of the negative control. The platelet counts of the test article were not statistically significant ($p>0.05$) when compared to the reference material.	Passed

Hemocompatibility – 40x Digital Optical Microscopy - comparative analysis of surface morphology	40x images were taken from multiple locations along the entire length of the subject device and the predicate control device to assess differences in surface characteristics and/or geometry. Although the catheters differed in color and transparency, there were no significant differences in geometry, surface morphology, or particulate contamination.	Passed

Shelf life: The accelerated shelf life testing for Ballast 088 Long Sheath has been conducted (T=1 year accelerated aging) with test results confirmed that all acceptance criteria were met. No new questions of safety or effectiveness are raised. Based on the results, we can conclude that Ballast 088 Long Sheath will perform as intended to the Design Specification. Ballast 088 Long Sheath will be labeled for 1-year shelf life.

Packaging: The packaging validation, T=1 year accelerated aging was performed on the Ballast 088 Long Sheath. The results from packaging testing conducted on Ballast 088 Long Sheath showed that the acceptance criteria were met. Therefore, we can conclude the Ballast 088 Long Sheath packaging will provide the adequate and effective protection and sterile barrier requirements.

Sterilization: Ballast 088 Long Sheath is sterilized using 100% Ethylene Oxide (EtO) gas in the same manner as FDA cleared predicate device, Neuron MAX™ System (K111380). Ballast 088 Long Sheath is sold sterile, for single use and single patient only. The sterilization validation was performed and is documented. The sterilization validation results showed that the sterilization dose and routine sterilization process was validated to achieve a SAL of 10^{-6} for the Ballast 088 Long Sheath.

Test Description	**Test Summary**	**Results**
Original Sterilization validation and Adoption	100% EO is used to sterilize the device to achieve a minimum SAL of 10^{-6}. The validation was conducted in accordance with ISO 11135. The original validation of the EO sterilization cycle of a worst-case device family was performed using one (1) fractional exposure cycle, three (3) half exposure cycles and one (1) full exposure cycle, overkill approach described in ISO 11135. The subject device was adopted to the original validated sterilization cycle by performing two (2) full cycles.	The validation study demonstrated that the sterilization process and equipment are capable of reliably and consistently sterilizing the devices to a minimum SAL of 10^{-6}. The BI results confirm the acceptable lethality of the sterilization cycle to achieve the required SAL of 10^{-6}. Fractional cycles, half cycles, and full cycles met the acceptance criteria. The subject device was successfully adopted to the original sterilization validation.
EO and ECH Residuals	EO and ECH residuals were measured per ISO 10993-7: 2008.	The residual traces of EO and ECH for the subject device are below the limits specified in ISO 10993-7.
Bacterial Endotoxin Levels	LAL testing was conducted in accordance with FDA guidance document (June 2012), USP<85>, and European Pharmacopeia BET 2.6.14	< 2.15 EU/device

CONCLUSIONS

The Ballast 088 Long Sheath met all specified criteria. We conclude that the subject device, Ballast 088 Long Sheath, is substantially equivalent in its intended use, design, material, performance,

and the underlying fundamental scientific technology used, to the predicate device, Neuron MAX™ System.