July 19, 2022

Balt USA, LLC
Ryan Kenney
Specialist, Regulatory Affairs
29 Parker
Irvine, California 92618

Re: K213435
Trade/Device Name: MAGIC Flow-Dependent Microcatheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA, QJP
Dated: June 16, 2022
Received: June 17, 2022

Dear Ryan Kenney:

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, 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

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)*
K213435

Device Name
MAGIC Flow-Dependent Microcatheter

Indications for Use *(Describe)*
The MAGIC Flow-Dependent Microcatheter is intended to access the peripheral and neuro vasculature for the controlled selective infusion of physician-specified embolization materials and diagnostic materials such as contrast media.

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: K213435

Applicant:	Balt USA, LLC 29 Parker Irvine, CA 92618 Registration No.: 3014162263
Contact Person:	Ryan Kenney Specialist, Regulatory Affairs Telephone: (949) 788-1443 Email: ryan.kenney@baltgroup.com

Date Summary Prepared:	July 19, 2022
Trade Name:	MAGIC Flow-Dependent Microcatheter
Common Name:	Catheter, Continuous Flush
Review Panel:	Cardiovascular, Neurology
Product Code:	KRA, QJP
Regulation Number:	21 CFR 870.1210, 21 CFR 870.1250
Regulation Name:	Continuous Flush Catheter
Device Classification:	Class II
Predicate Device:	MAGIC Infusion Catheter 510(k)#: K202366
Reference Device:	Marathon Flow Directed Micro Catheter 510(k)#: K202318

Device Description:
The MAGIC Flow-Dependent Microcatheter is designed with progressive suppleness and a rigid proximal shaft to allow control and navigability in the vascular system. By their diameter and progressive suppleness features, these catheters are specifically designed for catheterization of small diameter, sinuous distal vessels.

The catheter body and its distal tip (ring) are radiopaque to provide visibility under fluoroscopy. The MAGIC Flow-Dependent Microcatheter has an external hydrophilic coating which provides a lubricious surface during use.

A coated mandrel is included inside the MAGIC Flow-Dependent Microcatheter to provide support during product preparation and insertion through the guide catheter.

The MAGIC Flow-Dependent Microcatheter and accompanying support mandrel are provided sterile, non-pyrogenic, and intended for single use only.

Indications for Use:
The MAGIC Flow-Dependent Microcatheter is intended to access the peripheral and neuro vasculature for the controlled selective infusion of physician-specified embolization materials and diagnostic materials such as contrast media.

Device Comparison:

	MAGIC Infusion Catheter (K202366)	Marathon Flow Directed Micro Catheter (K202318)	MAGIC Flow-Dependent Microcatheter (K213435)
	Predicate Device	Reference Device	Subject Device
Indications for Use	The MAGIC Infusion Catheter is intended for regional infusion of contrast materials into selected vessels in the neurovasculature. The MAGIC Infusion Catheter may be used for controlled, regional infusion into selected vessels and is not intended for use in the coronary vasculature.	The Marathon Flow Directed Micro Catheter is intended to access the peripheral and neuro vasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and of diagnostic materials such as contrast media.	The MAGIC Flow-Dependent Microcatheter is intended to access the peripheral and neuro vasculature for the controlled selective infusion of physician-specified embolization materials and diagnostic materials such as contrast media.
Product Code	KRA	KRA, QJP	KRA, QJP
Dimensions			
Distal Outer Diameter	1.2 F, 1.5 F, 1.8 F	1.3 F	Same as K202366
Shaft Length	155 cm, 160 cm, 165 cm, 180 cm	165 cm	Same as K202366
Materials			
Catheter Body	PVC/Polyamide/Bismuth Carbonate	Grilamid/Pebax/Stainless-Steel/Adhesive/PTFE	Same as K202366
Hub	Grilamid	Polypropylene	Same as K202366
Hydrophilic Coating	Polyurethane/Polymer/Alcohol	Hyaluronic Acid/Acrylic Resin Binder	Same as K202366
Mandrel	Stainless Steel/Polystyrene/Polyamide/PTFE	N/A	Same as K202366
Marker Band	Platinum/Iridium	Platinum-Iridium Alloy	Same as K202366
Strain Relief	Grilamid	Elvax/Dynaflex	Same as K202366
Packaging Materials			
Carton	Multi-Layered Natural Fiber Composites	Natural, PTFE Tubing	Same as K202366
Pouch	Tyvek®	High-Density Polyethylene	Same as K202366
Stability			
Shelf Life	5 Years	1 Year	Same as K202366
Sterilization			
Method	Ethylene Oxide	Ethylene Oxide	Same as K202366

Biocompatibility:
There are no differences with respect to the materials or technological characteristics of the subject device in comparison to the predicate device. Therefore, no new biocompatibility testing was conducted.

Performance Data – Bench:
There are no differences with respect to the materials or technological characteristics of the subject device in comparison to the predicate device. To support the modification to the Indications for Use statement the following non-clinical bench testing was conducted for the subject device:

Test	Test Method Summary	Results
Compatibility with Embolic Materials	The subject device was evaluated using pre-defined acceptance criteria to demonstrate its ability to successfully deliver an array of embolic materials in a tortuous anatomical model.	Pass

Performance Data – Animal:
Balt USA, LLC did not conduct non-clinical animal testing because the subject device is identical to the predicate device with respect to technological characteristics and the modified Indications for Use statement does not raise new questions of safety and effectiveness and is supported through the successful completion of non-clinical bench testing using well-established scientific methods.

Performance Data – Clinical:
Balt USA, LLC did not conduct a clinical trial because the subject device is identical to the predicate device with respect to technological characteristics and the modified Indications for Use statement does not raise new questions of safety and effectiveness and is supported through the successful completion of non-clinical bench testing using well-established scientific methods.

Conclusion:
The intended use and technological characteristics of the subject device are the same or similar to that of the predicate and reference devices. The successful completion of non-clinical bench testing demonstrates that the subject device performs as intended and is substantially equivalent to the predicate device.