Balt USA, LLC
Corina Pierson
Director of Regulatory Affairs
29 Parker
Irvine, California 92618

January 29, 2021

Re: K202366
Trade/Device Name: MAGIC Infusion Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: December 16, 2020
Received: December 21, 2020

Dear Corina Pierson:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202366

Device Name
MAGIC Infusion Catheter

Indications for Use *(Describe)*
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.

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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MAGIC INFUSION CATHETER
510(K) SUMMARY

This 510(k) summary for the MAGIC Infusion Catheter is submitted in accordance with the requirements of 21 CFR 807.87(h) and 807.92.

DATE PREPARED:	December 11, 2020
APPLICANT:	Balt USA, LLC 29 Parker Irvine, CA, 92618 USA
CONTACT PERSON:	Corina Pierson, Director of Regulatory Affairs corina.pierson@baltgroup.com +1.949.788.1443
TRADE NAME:	MAGIC Infusion Catheter
COMMON NAME:	Continuous flush catheter
CLASSIFICATION NAME:	Catheter, Continuous Flush
DEVICE CLASSIFICATION:	Class II, 21 CFR 870.1210
PRODUCT CODE:	KRA
PREDICATE DEVICE:	MAGIC Infusion Catheter (K023351)
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.
DEVICE DESCRIPTION:	The MAGIC Infusion Catheters are microcatheters 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 Infusion Catheter has an external hydrophilic coating which provides a lubricious surface during use. A PTFE coated mandrel is included inside the MAGIC Infusion Catheter to provide support during product preparation and insertion through the guide catheter. The MAGIC Infusion Catheters and accompanying support mandrels

are provided sterile, non-pyrogenic, and intended for single use only.

TECHNOLOGICAL CHARACTERISTICS:

The 1.2F MAGIC Infusion Catheter (subject device) is substantially equivalent to the predicate with respect to similar materials of construction, indications for use (intended use) and technological characteristics. A comparison of the Subject device with the Predicate is summarized in the table below.

	1.5F MAGIC Infusion Catheter (K023351) (Predicate Device)	**1.2F MAGIC Infusion Catheter (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.	Same
Catheter Body	PVC, Polyamide, Bismuth Carbonate	Same
Mandrel	Stainless Steel / Polystyene / Polyamide / PTFE	Same
Hydrophilic Coating	Polyurethane / Polymer / Alcohol	Polyurethane / Polymer / Alcohol (minor modification to polymer + alcohol %)
Strain Relief	Grilamid	Same
Hub	Grilamid	Same
Shaft length	155 cm, 165cm	155cm, 165cm, 180cm
Sizes	1.5F and 1.8F	1.2F, 1.5F and 1.8F
Tip Marker Band	Platinum / iridium	Platinum / iridium
Carton	Multilayered, natural fiber composites	Same
Pouch	Tyvek®	Same
Shelf Life	5 Years	Same
Sterilization	Ethylene Oxide (EO)	Same
Use	Single Use	Same

PERFORMANCE DATA [807.92(b)]

Bench testing was conducted to evaluate the performance of the 1.2F MAGIC Infusion Catheter (subject device). The successful test results establish device integrity suitable for its intended clinical use and support substantial equivalence to the 1.5F MAGIC Infusion Catheter (predicate device). See table below for the bench test summary results.

Bench Test	Acceptance Criteria	Results
Dimensional and Physical Attributes Visual Inspection	Shall meet the required dimensional measurements and physical attributes per established specifications. Shall meet the established acceptance criteria for surface defects and contamination.	PASS
Torque Strength Test	Catheters shall withstand the established acceptance criteria for torque strength without breaking.	PASS Device integrity suitable for intended clinical use
Catheter Tensile Test	Shall meet ISO 105551-1, Annex B	PASS
Corrosion Resistance	Shall meet ISO 105551-1, Annex A	PASS
Flow Rate	Reference Data	N/A
Dynamic Pressure	Catheters shall withstand the maximum infusion pressure (as indicated on the product labeling) under dynamic conditions. (Adopted from ISO 105551-1)	PASS Device met maximum labeled infusion pressure
Static Burst Pressure	Catheters shall withstand the maximum infusion pressure (as indicated on the product labeling) under static conditions. (Adopted from ISO 105551-1)	PASS Device integrity suitable for intended clinical use
Pressure and Hub Test (Fluid Leakage)	Catheters shall not leak when injected with water at the maximum infusion pressure (as indicated on the product labeling) for a 30 second duration.	PASS Device integrity suitable for intended clinical use
Simulated Use / Coating Lubricity and Durability	Catheters shall be tracked using a benchtop model under simulated use conditions per product IFU, and meet established acceptance criteria for product performance, trackability, coating lubricity and durability.	PASS Results comparable to predicate device
Kink Resistance	Catheter body shall be wrapped around different pin gauges at various locations and meet the expected acceptance criteria for kink resistance. No kinks shall be noted during Simulated Use.	PASS Results comparable to predicate device

Bench Test	Acceptance Criteria	Results
Radiopacity	Marker band shall be detectable under radiographic techniques. (Per ASTM F640-12)	PASS
Particulates	Shall meet USP <788> criteria No particulates shall be noted pre and post Simulated Use.	PASS Results comparable to predicate device

Summary of Biocompatibility Testing

The 1.2F MAGIC Infusion Catheter was assessed for biocompatibility in accordance with ISO 10993-1 "*Biological Evaluation of Medical Devices – Part 1: Evaluation of Testing within a Risk Management Process."* The catheter is considered an externally communicating medical device with circulating blood contact for less than 24 hours. See table below for tests performed and results.

Biocompatibility Test	Test Method	Results
Cytotoxicity – MEM Elution Test	ISO 10993-5	PASSED
Cytotoxicity –Agar Overlay Assay	ISO 10993-5	PASSED
Sensitization – Guinea Pig Maximization Test	ISO 10993-10	PASSED
Irritation – Intracutaneous Reactivity	ISO 10993-10	PASSED
Acute Systemic Toxicity – Systemic Injection Test	ISO 10993-11	PASSED
Systemic Toxicity – Rabbit Pyrogen Test	ISO 10993-11	PASSED
Hemocompatibility – Hemolysis	ISO 10993-4 / ASTM F756	PASSED
Hemocompatibility – Complement Activation	ISO 10993-4	PASSED
Hemocompatibility – Thrombogenicity: Canine Model	ISO 10993-4	PASSED
Hemocompatibility – Thrombogenicity: Partial Thromboplastin Time Assay	ISO 10993-4 / ASTM F2382-18	PASSED

Biocompatibility Test	Test Method	Results
Hemocompatibility – Thrombogenicity: Platelet/ Leukocyte Count Assay	ISO 10993-4 / ASTM F2888-19	PASSED

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The data presented demonstrates that the technological characteristics of the subject device (1.2F MAGIC Infusion Catheter) are substantially equivalent to the technological characteristics of the previously cleared 1.5F MAGIC Infusion Catheter (K023351). Substantial equivalence is determined based on the following similarities:

- Same intended use/indications for use;
- Same principles of operation;
- Same fundamental scientific technology;
- Incorporates similar basic infusion catheter design;
- Incorporates similar materials of construction.

CONCLUSION

Upon review of the performance data, intended use, design, materials of construction, principles of operation and fundamental scientific technologies, the 1.2F MAGIC Infusion Catheter (Subject device) is determined to be substantially equivalent to the 1.5F MAGIC Infusion Catheter (Predicate device) previously cleared under K023351. The information and data provided identify no new safety or effectiveness concerns. BALT USA believes that substantial equivalence has been demonstrated.