June 5, 2026

Balosmark, Inc.
% Nancy Frame
Regulatory Consultant
Gateway Medical Consulting Services, LLC
5 Scotch Pine Ln
St. Paul, Minnesota 55127

Re: K260289
Trade/Device Name: Perfect-O Ostial Positioning Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: May 6, 2026
Received: May 7, 2026

Dear Nancy Frame:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LYDIA S. GLAW -S

Digitally signed by LYDIA S. GLAW -S
Date: 2026.06.05 16:50:21 -04'00'

Lydia Glaw
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260289

Device Name
Perfect-O Ostial Positioning Catheter

Indications for Use *(Describe)*
The Perfect-O Ostial Positioning Catheter is intended for use in aorto-ostial procedures to introduce and position stents and other interventional devices within the coronary and peripheral vasculature. In addition, the Perfect-O Ostial Positioning Catheter is intended to facilitate the alignment of interventional devices and function as an alignment tool. The Perfect-O Ostial Positioning Catheter is not intended for use and has not been evaluated for use 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

[As required by 21 CFR 807.92]

Date Prepared: May 05, 2026

510(k) Number: K260289

Submitter's Name / Contact Person

Manufacturer
Balosmark, Inc.
2348 Sheffield Drive
Kalamazoo, MI 49008
Org ID # 815021

Contact Person
Nancy Frame
Regulatory Consultant
Tel: 763.300.3167 (direct)
nframe@gatewayMCS.com

General Information

Trade Name	Perfect-O Ostial Positioning Catheter
Common / Usual Name	Percutaneous Catheter
Classification Name	21 CFR 870.1250, DQY, Class II
Predicate Device	K122089, Ostial Pro Stent Positioning System (Merit Medical Systems, Inc)

Device Description

The Perfect-O is a medical-grade, disposable catheter designed to provide consistent and precise stent implantation in aorto-ostial lesions during coronary or peripheral interventional procedures. It consists of a flexible distal shaft that can be placed at the targeted aorto-ostial location. An atraumatic, compliant balloon inflated with saline/contrast media, and a radiopaque marker at the distal tip of the catheter facilitates precise stent placement at the aorto-ostial lesion.

The Perfect-O consists of three (3) components:

- Ostial Positioning Catheter: The primary component of the Perfect-O system is a single-use catheter composed of a proximal hub, hypotube, flexible distal shaft, and compliant distal balloon. The proximal hub features a standard luer connection for attachment to the supplied stopcock and syringe, allowing controlled balloon inflation and deflation. The hypotube extends distally from the hub, providing pushability and containing the inflation lumen that delivers the saline/contrast mixture to the balloon. It terminates near the proximal end of the flexible shaft, which includes a separate lumen that permits passage of interventional devices. The compliant distal balloon inflates to act as a temporary positioning aid against the vessel ostium, facilitating accurate stent alignment. A radiopaque marker near the distal tip provides fluoroscopic visibility during positioning and deployment.
- 2-Way Stopcock: A single-use stopcock supplied with the system allows controlled balloon inflation and deflation. It connects the proximal hub of the ostial positioning catheter to the syringe and provides fluid isolation during the procedure.

- Syringe: A single-use syringe is provided for balloon inflation and deflation using a saline/contrast mixture as described in the Instructions for Use (IFU). The syringe interfaces with the stopcock and catheter hub to enable controlled delivery and withdrawal of inflation media.

Indications for Use

The Perfect-O Ostial Positioning Catheter is intended for use in aorto-ostial procedures to introduce and position stents and other interventional devices within the coronary and peripheral vasculature. In addition, the Perfect-O Ostial Positioning Catheter is intended to facilitate the alignment of interventional devices and function as an alignment tool. The Perfect-O Ostial Positioning Catheter is not intended for use and has not been evaluated for use in the neurovasculature.

Comparison of Technological Characteristics with the Predicate Device

A comparison of the technological characteristics between the Perfect-O Ostial Positioning Catheter and the predicate device is provided in the following table. The differences are highlighted.

Characteristic	Primary Predicate Device	Subject Device
	Ostial Pro Stent Positioning System	**Perfect-O Ostial Positioning Catheter**
510(k)	K122089	TBD
Manufacturer	Merit Medical Systems, Inc.	Balosmark, Inc
Product Class	II	II
Product Classification	**870.1330**	**870.1250**
Product Code	**DQX**	**DQY**
Indications for Use	The Ostial Pro Stent Positioning System is intended for use in aorta-ostial procedures to introduce and position stents and other interventional devices within the coronary and peripheral vasculature. In addition, the Ostial Pro Stent Positioning System is intended to facilitate the alignment of interventional devices and function as an alignment tool.	The Perfect-O Ostial Positioning Catheter is intended for use in aorto-ostial procedures to introduce and position stents and other interventional devices within the coronary and peripheral vasculature. In addition, the Perfect-O Ostial Positioning Catheter is intended to facilitate the alignment of interventional devices and function as an alignment tool. The Perfect-O Ostial Positioning Catheter is not intended for use and has not been evaluated for use in the neurovasculature.
Contraindication	If other interventional devices are used in conjunction with the Ostial PRO Stent Positioning System, refer to specific manufacturer's product labeling for intended use, contraindications and potential complications associated with that device.	**None**
Anatomical sites	Coronary and peripheral vasculature	Coronary and peripheral vasculature

Characteristic	Primary Predicate Device	Subject Device
	Ostial Pro Stent Positioning System	**Perfect-O Ostial Positioning Catheter**
Product Description	The Ostial PRO Stent Positioning System is a medical grade, disposable guide wire system designed to provide consistent and precise stent implantation in aorto-ostial lesions during coronary or peripheral interventional procedures. It consists of a flexible guide wire shaft that can be easily and accurately placed in the targeted aorto-ostial location. Low profile, atraumatic, radiopaque expandable "feet" at the distal tip of the guide wire system facilitate precise stent placement in the aorto-ostial lesion.	The Perfect-O Ostial Positioning Catheter, a sterile, single-use intravascular device, is designed to enable precise stent placement in aorto-ostial lesions during coronary or peripheral interventional procedures. Its flexible, coiled shaft, combined with a distal atraumatic, compliant balloon and a distal radiopaque marker band, facilitates visualization and positioning. The device is designed to minimize the risk of stent misplacement, potentially reducing procedure time and complications, thereby improving patient safety.
Single Use or Reusable	Single Use	Single Use
Materials of construction	**Nitinol, Gold Plating**	**Pebax, PTFE, Vestamid, Stainless Steel, Hydrophilic Coating, polyimide, polycarbonate, ProFlex, Platinum Iridium, Cyanoacrylate, UV Adhesive**
Catheter Tip	**Nitinol wire, gold plated legs**	**Compliant Balloon**
Compatible Guide Catheter	6F, **7F, 8F**	6F
Effective ID	**0.050", 0.058", 0.068"**	**0.049"**
Working Length	127 cm	127 cm
Method of Sterilization	EO	EO
Coating	N/A	**Hydrophilic Coating**
Radiopacity	Yes	Yes

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Performance Data

Biocompatibility

The biocompatibility evaluation for the Perfect-O Ostial Positioning Catheter was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The Perfect-O Ostial Positioning Catheter is considered an externally communicating device in contact with circulating blood and tissue for a limited period of time (<24 hours) during use. The battery of tests included the following:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Pyrogenicity
- Hemolysis
- Complement Activation
- Thrombogenicity

Performance Data - Bench

The device design was verified through bench testing. Tests included dimensional verification, simulated use, tensile strength, flexibility and kink, torque strength, radiopacity, corrosion resistance, structural integrity, balloon rated burst pressure, balloon rated burst volume, balloon compliance, balloon inflation and deflation time, coating integrity, and particulate evaluation.

Conclusion

Based on the indications for use, biocompatibility, bench and usability testing, the subject Perfect-O Ostial Positioning Catheter did not raise any new questions of safety or effectiveness compared to the predicate. The Perfect-O Ostial Positioning Catheter is substantially equivalent to the Ostial Pro Stent Positioning System.