May 31, 2024

Vascular Solutions LLC
Becky Astrup
Pr. Regulatory Product Specialist
6464 Sycamore Court North
Minneapolis, Minnesota 55369

Re: K233729

Trade/Device Name: Ringer perfusion balloon catheter, 2.00 x 20mm (5881);
Ringer perfusion balloon catheter, 2.50 x 20mm (5882);
Ringer perfusion balloon catheter, 2.50 x 30mm (5883);
Ringer perfusion balloon catheter, 3.00 x 20mm (5884);
Ringer perfusion balloon catheter, 3.00 x 30mm (5885);
Ringer perfusion balloon catheter, 3.50 x 20mm (5886);
Ringer perfusion balloon catheter, 3.50 x 30mm (5887);
Ringer perfusion balloon catheter, 4.00 x 20mm (5888);
Ringer perfusion balloon catheter, 4.00 x 30mm (5889);
Ringer perfusion balloon catheter, 4.50 x 20mm (5890);
Ringer perfusion balloon catheter, 5.00 x 20mm (5891)

Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: May 2, 2024
Received: May 2, 2024

Dear Becky Astrup:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Brian D. Pullin -S

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233729

Device Name
Ringer perfusion balloon catheter

Indications for Use *(Describe)*
The Ringer Perfusion Balloon Catheter is indicated for balloon dilatation of coronary artery or coronary bypass graft stenoses where the physician desires distal blood perfusion during balloon inflation for the purpose of improving myocardial perfusion.

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 1, 2024

510(k) Number: _K233729_

Submitter's Name / Contact Person

Manufacturer
Vascular Solutions LLC
6464 Sycamore Court North
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

Contact Person
Becky Astrup
Pr. Regulatory Product Specialist
Tel: 763-762-2601

General Information

Trade Name	Ringer perfusion balloon catheter
Common / Usual Name	Catheter
Classification Name	21 CFR 870.5100, LOX, Percutaneous Transluminal Coronary Angioplasty Catheters, Class II
Predicate Device	K153682, Chocolate XD PTCA Balloon Catheter (Vascular Solutions) The Chocolate XD PTCA balloon catheter has not been subject to a design related recall.

Device Description

The Ringer perfusion balloon catheter is a rapid exchange catheter with a spiral-shaped inflatable balloon on the distal end and a wire lumen for delivery over a ≤ 0.014" guidewire. The inflated spiral balloon approximates a hollow cylinder. Radiopaque markers at the proximal and distal end of the balloon facilitate visualization and intravascular placement of the catheter prior to inflation. The catheter shaft has positioning marks located at 95cm (single mark) and 105cm (double mark) from the distal tip. The Ringer perfusion balloon catheter has been sterilized with ethylene oxide.

Indications for Use

The Ringer Perfusion Balloon Catheter is indicated for balloon dilatation of coronary artery or coronary bypass graft stenoses where the physician desires distal blood perfusion during balloon inflation for the purpose of improving myocardial perfusion.

The Indications for Use statement for the Ringer Perfusion Balloon Catheter is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for the balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.

Comparison of Technological Characteristics with the Predicate Device

The subject device and predicate device have the same intended use and the indications for use for the subject device fall within the intended use of the predicate device. Differences between the subject device indications for use and predicate device indications for use are supported by benchtop, animal, and clinical tests.

The Ringer perfusion balloon catheter and the predicate device have the same technological characteristics with respect to:

- Conditions of Use
- General Principles of Operation
- Cutting/Scoring Features (none)
- Materials
- Catheter Shaft Design and Configuration
- Guidewire and Guide Catheter Compatibility
- Balloon Length
- Balloon Inflation Time
- Radiopaque Markers
- Catheter Length
- Packaging
- Sterilization
- Shelf Life

The following technological differences exist between the subject and predicate device:

- Ancillary Device Delivery
- Balloon Design
- Distal Perfusion Mechanism
- Crossing Profile
- Balloon Diameter
- Nominal Pressure
- Rated Burst Pressure
- Balloon Deflation Time

Results of benchtop, animal, and clinical tests demonstrate that the technological characteristics of the subject device do not raise different questions of safety and effectiveness and that the subject device is substantially equivalent to the predicate device.

Performance Data

The following performance data were provided in support of substantial equivalence.

Biocompatibility Tests:

The biocompatibility evaluation for the Ringer perfusion balloon catheter device was conducted in accordance with the FDA Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*, September 2023

and 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 battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Materia Mediated Pyrogenicity
- Hemolysis
- Complement Activation
- Thrombogenicity

The Ringer perfusion balloon catheter is considered an external communicating device contacting circulating blood for a limited duration (<24 hours).

Bench Tests:

- Dimensional and Visual Verification
- Balloon Preparation, Deployment and Retraction
- Balloon Rated Burst Pressure
- Balloon Fatigue
- Balloon Compliance
- Balloon Inflation and Deflation Time
- Catheter Bond Strength
- Tip Pull Test
- Flexibility and Kink
- Torque Strength
- Radiopacity
- ISO 80369 Hub Verification

Animal Tests:

The safety of the Ringer perfusion balloon catheter was evaluated during simulated clinical use in a swine model. The testing was performed in accordance with 21 CFR Part 58 for Good Laboratory Practice (GLP) for Non-Clinical Laboratory Studies.

The primary objective of demonstrating safety of the Ringer perfusion balloon catheter was exhibited in this study in terms of the measured adverse events, procedural data, gross necropsy, histopathology, and clinical observations. Normal, TIMI 3 perfusion was maintained to all vasculature distal to the test article for the duration of inflation. Thrombogenicity scores demonstrated no to minimal thrombus formation. Additionally, no significant visual changes observed from baseline to terminal time points through angiographic evaluation.

Clinical Tests:

Clinical data was collected for the Ringer perfusion balloon catheter to support substantial equivalence (G200321, 'Ringer PTCA Study'). The objective of the Ringer PTCA study was to demonstrate performance of the Ringer Perfusion Balloon Catheter for dilatation/pre-dilatation of coronary stenoses during percutaneous coronary intervention (PCI). The secondary objective was to demonstrate maintenance of coronary blood flow distal to the inflated Ringer device thereby enabling prolonged balloon inflation (balloon inflation equal to or greater than one minute).

<u>Primary Effectiveness Endpoint</u>

The primary efficacy endpoint was device procedural success consisting of successful delivery, inflation, deflation, and removal of the study device; no vessel perforation, flow-limiting vessel dissection, no reduction in TIMI flow from baseline, and no clinically significant arrhythmias requiring medical treatment or device intervention following dilatation with the study device; achievement of final TIMI

flow grade of 3 at the conclusion of the PCI procedure for the target lesion. The primary efficacy endpoint was met in 57/60 (95%) of the subjects.

Primary Safety Endpoint

The study primary safety endpoint of occurrence of clinically relevant events during prolonged balloon inflations and freedom from MACE at hospital discharge was met in 95% (57/60) of the subjects.

Secondary Efficacy Endpoint

The secondary efficacy endpoint for the study was successful PCI defined as final residual stenosis ≤20% diameter stenosis (in-stent) or ≤ 50% diameter stenosis (stand-alone balloon) by visual angiographic estimation and freedom from MACE at hospital discharge; maintenance of TIMI-2 or -3 flow into distal coronary bed during study device inflation. The secondary efficacy endpoint of successful PCI was met in 93% (56/60) of the subjects.

Secondary Efficacy Endpoint

The secondary safety endpoint evaluated tolerance of at least one study device inflation equal to or greater than one minute (prolonged inflation) at target site. The secondary safety endpoint of tolerance of at least one Ringer perfusion balloon catheter prolonged inflation at target site was met in 50/60 (83.3%) of subjects.

Summary

Procedural success was achieved in 95% of cases with no serious adverse events attributable to the subject device. Maintenance of TIMI II or III flow into distal coronary bed during Ringer perfusion balloon inflation was achieved in 100% of cases.

This clinical data demonstrates that the subject device is appropriate for use in PTCA procedures. The clinical data raised no new questions of safety and effectiveness compared to the predicate device, supporting that the subject device is substantially equivalent to the predicate device.

Conclusions

The subject and predicate devices share the same intended use and fundamental scientific technology, including principle of operation. Differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness as demonstrated by bench, animal, and clinical tests. Non-clinical and clinical performance and safety evaluations support substantial equivalence of the Ringer perfusion balloon catheter to the predicate device.