December 12, 2025

Strait Access Technologies Holdings
℅ Robert Packard
Regulatory Consultant
Medical Device Academy
345 Lincoln Hill Rd
Shrewsbury, Vermont 05738

Re: K243184
Trade/Device Name: SAT CenterFlow Molding Balloon Catheter (IN20-00313)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY

Dear Robert Packard:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on June 25, 2025. Specifically, FDA is updating this substantial equivalence (SE) letter as an administrative correction to include the correct version of the 510(k) Summary for K243184.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Rohini Retarekar, OHT2: Office of Cardiovascular Devices, (240) 402-2750, rohini.retarekar@fda.hhs.gov.

Sincerely,

Rohini Retarekar -S

for Carmen Gacchina Johnson, Ph.D.
Assistant Director
DHT2B: Division of Circulatory Support,
Structural, and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

June 25, 2025

Strait Access Technologies Holdings
℅ Robert Packard
Regulatory Consultant
Medical Device Academy
345 Lincoln Hill Rd
Shrewsbury, Vermont 05738

Re: K243184
Trade/Device Name: CenterFlow Molding Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 30, 2024
Received: May 23, 2025

Dear Robert Packard:

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.

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,

Rohini Retarekar -S

for Carmen Gacchina Johnson, Ph.D.
Assistant Director
DHT2B: Division of Circulatory Support,
Structural, and Vascular 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)*
K243184

Device Name
CenterFlow Molding Balloon Catheter

Indications for Use *(Describe)*
The CenterFlow Molding Balloon Catheter is intended to assist in the dilatation of self-expanding endoprostheses in large diameter vessels.

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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SAT CenterFlow Molding Balloon Catheter;
510(k) Summary
K243184

Date: 19 June 2025

Applicant Name: Strait Access Technologies Holdings (Pty) Ltd

Applicant Address: 313 Chris Barnard Building
Anzio Road
University of Cape Town Medical Campus
Observatory
Cape Town
7925

Correspondent Name: Medical Device Academy

Correspondent Address: 345 Lincoln Hill Rd
Shrewsbury, VT
05738
United States

Correspondent Tel: +1 802 281 4381

Correspondent Contact: Mr. Rob Packard

Correspondent Email: rob@fdaestar.com

1. Device Name

Device Trade Name:	CenterFlow Molding Balloon Catheter
Common Name:	Percutaneous Catheter, Balloon Catheter
Classification Name:	Catheter, Percutaneous
Product Code:	DQY
Regulation Number:	870.1250

2. Legally Marketed Predicate Device(s)

Device Name	Manufacturer	510(k) Number	Product Code
Tri-Lobe Balloon Catheter	W.L Gore & Associates	K081799	DQY

3. Device Description Summary

The CenterFlow Molding Balloon Catheter is intended to assist in the dilatation of self-expanding endoprostheses in large diameter vessels. When used in its indications for use, it is a flow-permissive, over-the-wire, single-use device comprised of two elongated non-compliant nylon balloons that are attached to and within a nitinol support frame. The two elongated balloons are constrained in a zig-zag arrangement by the nitinol support frame. Upon inflation, this configuration enables expansion of the device head through balloon straightening, to assist the dilatation of self-expanding endoprostheses in large diameter vessels. Expansion of the zig-zag balloon configuration creates a central orifice permitting maintained hemodynamic flow during the molding procedure.

The inflation lumen is 9 Fr and is made of PEBAX 72D. A co-axial PEBAX 72D guidewire lumen runs through the inflation lumen and device head and terminates into a distal polycarbonate tip. Two platinum-iridium markers provide angiographic visualization of the distal and proximal balloon edges to facilitate intravascular balloon placement prior to inflation. The catheter has a working length of 110 cm and it connects proximally to a standard Y-connector at the proximal end. The Y-connector allows for separation of two lumens - an angled luer-lock hub to inflate and deflate the balloon and a straight luer-lock hub which accepts a 0.035” guidewire. The device is deflated and inserted over the guidewire through the hemostasis valve of a transfemoral introducer sheath.

4. Intended Use/Indications for Use

The SAT CenterFlow Molding Balloon Catheter is intended to assist in the dilatation of self-expanding endoprostheses in large-diameter vessels.

5. Comparison of Essential Design Features

Design Features - Summary	CenterFlow Molding Balloon Catheter	Gore Tri-Lobe Balloon Catheter
Device Design Description - Overall	A flow-permissive balloon catheter that assists in the dilatation of self-expanding endoprostheses in large vessels.	A lobed balloon catheter that assists in the dilatation of self-expanding endoprostheses in large vessels without complete blockage of aortic blood flow.
	Consists of two elongated nylon balloons attached to, and	Consists of three polyurethane balloons mounted on the leading

	contained within a nitinol support frame.	edge on a multi-lumen catheter shaft.
	The elongated balloons, constrained in a zig-zag arrangement within the frame, expand through balloon straightening, creating a central orifice that maintains hemodynamic flow.	Each of the three inflation lumens communicates with one of the balloons, and an inflation port communicates with all the lumens.
	A Y-connector allows for the separation of two lumens and a straight luer-lock hub accepts a 0.035” guidewire.	The guidewire lumen allows for a 0.035” guidewire.
Materials of Use	The device uses radiopaque marker bands.	Same
	The balloons are made of nylon.	The balloons are made of polyurethane.
Dimensions	Balloon diameter, 20-46 mm Catheter shaft – 113 cm Introducer sheath compatible, 18 Fr	Balloon diameter for BCM1634, 16-34 mm for BCL2645, 26-42 mm Catheter shaft – 108 cm Introducer sheath compatible, 18 Fr
Relevant Standards	ISO 10555-4 Intravascular catheters – sterile and single use catheters, part 4 Balloon dilatation catheters, 2023-11. ISO 10555-14 Intravascular catheters – sterile and single use catheters, part 1 General requirements, 2023-11.	Same

6. Non-Clinical Tests Summary & Conclusions

The non-clinical testing conducted showed that the subject device is substantially equivalent to the predicate device. Below is an indication of the tests performed:

- Benchtop performance testing
- Biological Safety Evaluation and Biocompatibility
- In vivo safety evaluation
- Packaging validation
- Shelf-life validation
- Usability Engineering evaluation