September 29, 2025

South53, LLC.
% Octavio Cruz-Uribe
Director of Regulatory Affairs
Biologics and Medical Device Consulting Group (BioMDg)
930 Tahoe Blvd, Ste 802 PMB 323
Incline Village, Nevada 89451

Re: K252441
Trade/Device Name: Primero Safe Access System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: August 4, 2025
Received: August 4, 2025

Dear Octavio Cruz-Uribe:

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,

FINN E. DONALDSON -S

Digitally signed by FINN E. DONALDSON -S
Date: 2025.09.29 09:13:28 -04'00'

for
Misti Malone
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)*
K252441

Device Name
Primero Safe Access System

Indications for Use *(Describe)*
The Primero Safe Access System is intended to facilitate placing a catheter through the skin into a vein or artery. The introducer needle is used in facilitating entry through the skin into a vein or artery to provide a conduit for the guidewire. The guidewire is an accessory device which is used for placement of a catheter or sheath in the vein or artery.

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

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(K) NUMBER	K252441
DATE PREPARED	August 4, 2025
APPLICANT	South53, LLC 27131 Calle Arroyo, Ste 1722 San Juan Capistrano, CA 92675
OFFICIAL CORRESPONDENT	Octavio Cruz-Uribe, PhD Biologics and Medical Device Consulting Group (BioMDg) 930 Tahoe Blvd, STE 802 PMB 323 Incline Village, NV 89451 Tel: (541) 908-2591 tavi@BioMDG.com
TRADE NAME	Primero Safe Access System
COMMON NAME	Catheter Introducer
DEVICE CLASSIFICATION	Regulation No: 21 CFR §870.1340 Product Code: DYB Class: II
PREDICATE DEVICE **REFERENCE DEVICE**	Pinnacle Precision Access System (K111606) Arrow Nitinol Wire w/ Advancer (K241784)

DESCRIPTION OF THE DEVICE:

The Primero Safe Access System (SAS) is a catheter introducer that facilitates a quick approach for placement of a guidewire during the introduction of a catheter for vascular access. The Primero SAS combines an introducer needle, guidewire, advancer, and storage tube into a single integrated device to promote ease of use and quick access by the healthcare provider. The introducer needle consists of an 18Ga stainless steel needle with an echogenic tip and terminates on the proximal end with a colored translucent standard female luer lock hub. The introducer needle has an enhanced echogenic tip, that has been slightly modified to incorporate a small bulb-like feature at the proximal end of the tip bevel to enhance ultrasonic visualization during vascular access. The introducer needle is secured to the advancer through a luer lock connector at the distal end of the advancer. The advancer is a light-weight polymer handpiece that allows the user to grip the entire setup while introducing the needle into the vessel and then advancing the guidewire through the needle by either ‘thumb” or ‘two-finger” advancing based on the preference of the user. A cutout in the advancer handpiece wire path exposes the guidewire and conveniently allows the user to advance the guidewire with their fingers without having to let go

of the handpiece. An internal path within the handpiece feeds the guidewire from a storage tube into the introducer needle. The looped storage tube is connected to the proximal end of the advancer and holds a spooled pre-loaded guidewire ready for deployment. A back stop has been inserted into the tube at the proximal end to prevent a guidewire from being over-retracted from the advancer. The Primero SAS is pre-loaded with a commercially available guidewire (previously cleared under K142393) ready for deployment through the introducer needle once placed in the target vessel. The guidewire is comprised of an uncoated nitinol core wire that is tapered at the distal tip where a stainless-steel coil is secured over the full-length of the core. The South53 Primero Safe Access System (SAS) integrates all the necessary elements into a single device to complete the Seldinger technique as part of a vascular access procedure.

The Primero SAS is provided sterile and is intended for single patient use. The device is not intended to be re-sterilized or re-used.

INDICATIONS FOR USE:

The Primero Safe Access System is intended to facilitate placing a catheter through the skin into a vein or artery. The introducer needle is used in facilitating entry through the skin into a vein or artery to provide a conduit for the guidewire. The guidewire is an accessory device which is used for placement of a catheter or sheath in the vein or artery.

SUBSTANTIALLY EQUIVALENT TO:

The Primero Safe Access System (SAS) is substantially equivalent in intended use and technological features to the predicate, Pinnacle Precision Access System (K111606), and reference devices, the Arrow Nitinol Wire w/ Advancer (K241784).

SUMMARY OF TECHNOLOGICAL CHARACTERISTIC SIMILARITIES/DIFFERENCES:

The Primero SAS is substantially equivalent in intended use and technological features to the Pinnacle Precision Access System (K111606) identified as the predicate. Both devices are intended to be used to facilitate placing a catheter through the skin into a vein or artery. The same technological approach to facilitate the introduction of a catheter into a vessel is employed by both devices. Both devices include an introducer needle with an echogenic tip, a guidewire in a storage tube, and a guidewire inserter (advancer). Secondarily, the Teleflex spring-wire guide w/ Arrow Advancer (most recently cleared as the Arrow Nitinol Wire under K241784), was used as a reference device to support the substantial equivalence of the guidewire and advancer provided with the Primero SAS.. The guidewires included in the subject, predicate and reference devices have the same intended use and function.

There are several minor differences between the proposed subject device and the predicate/reference devices. Both introducer needles for the subject and predicate devices are echogenic, however the SAS device includes a small echogenic bulb to aid visibility of the needle location at the distal end. There is also a small difference in the available introducer needle diameter between the subject (18Ga) and predicate device (19-21Ga). However, the

difference in needle diameter is negligible and does not raise any new questions of safety and effectiveness. The pre-loaded guidewire length is also different (70cm for the subject device vs. 45cm for K111606). The reference device, K241784 has a length of 30-68cm and was used to support the substantial equivalence of this attribute. The Primero SAS will only be configured with one size introducer needle and guidewire which falls within the range of size options for the predicate device. There are no other technological differences between the subject and predicate/ reference devices.

SUMMARY OF NONCLINICAL TESTING:

A comprehensive performance bench testing program was executed for the Primero SAS to verify the function, performance, and safety of the device. All testing was performed on sterile finished test units of the Primero SAS. As part of performance bench testing the following were performed:

Test Description	Test Method	Conclusion
Dimensional and Physical Attribute Verification	Primero SAS were inspected to meet all defined critical dimensional specifications and required physical attributes.	**PASS**. The subject devices met the specified physical and dimensional criteria.
Insertion / Penetration Force Testing	The insertion / penetration force of the Primero SAS was verified to be comparable to meet required insertion force limits through a simulated skin material.	**PASS**. The insertion / penetration forces met all acceptance criteria.
Particulate Evaluation	Particulates generated during deployment of the Primero SAS was verified in a simulated model to be acceptable in comparison to the reference device.	**PASS**. Particulate matter released during the use of the subject device was comparable to predicate device.
Mechanical Strength Testing	Primero SAS was verified to be capable of withstanding mechanical forces expected during the use of the device to place a guidewire. Testing included tensile strength testing and bond/joint pull testing.	**PASS**. The subject device demonstrated the ability to withstand mechanical forces without failure.
Echogenicity Testing	The Primero SAS needle tip was confirmed to be sufficiently visible under ultrasound under simulated conditions comparable to the predicate device.	**PASS**. The subject devices were demonstrated to be sufficiently visible under ultrasound.

Test Description	Test Method	Conclusion
Simulated Use	Primero SAS were validated for the following functional and performance attributes of the device during simulated use conditions: • Puncture of simulated skin • Guidewire placement (advancement, retraction) • Needle, advancer removal • Repeatability • Over retraction	**PASS**. The subject device demonstrated the successful ability to deploy a guidewire into the target vessel without difficulty or damage to the device.
Usability Evaluation	The Primero SAS was delivered in simulated clinical conditions to assess the users' ability to use the device and reliably deploy a guidewire.	**PASS**. The subject device was rated similar to the predicate/reference devices for ease of use and performance.

Overall, testing confirms the functionality of Primero SAS and supports its substantial equivalence to the predicate/reference devices.

BIOCOMPATIBILITY:

The Primero SAS is characterized as an externally communicating device with direct circulating blood contact of a limited duration (A; ≤24h). Biocompatibility testing was performed by independent testing facilities on finished and sterilized product in accordance with ISO 10993-1:2018 "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing" as specified in 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' dated September 8, 2023. Based on the contact type and duration, the following recommended tests from the ISO 10993-1 standard and the corresponding FDA guidance were performed. All biocompatibility tests for the Primero SAS passed their corresponding acceptance criteria.

Biocompatibility Test	Pass/Fail	Results and Conclusions
Cytotoxicity: MEM Elution Assay w/ L-929 Cells (ISO 10993-5)	**Pass**	No evidence of causing cell lysis or toxicity.
Guinea Pig Maximization Sensitization Test (ISO 10993-10)	**Pass**	The test article did not elicit a sensitization response.
Intracutaneous Reactivity Test (ISO10993-10)	**Pass**	The test article was deemed a non-irritant.
Acute Systemic Injection Test (ISO 10993-11)	**Pass**	None of the animals on study were observed with abnormal clinical signs indicative of toxicity during the test period.

Biocompatibility Test	Pass/Fail	Results and Conclusions
Rabbit Pyrogen Test (Material Mediated) (ISO 10993-11)	**Pass**	The temperature increases for the test animals during the 3-hour did not exceed the test limit ≥0.5 °C for the maximum individual temperature rise.
Hemolysis – Direct Method (ASTM F756 / ISO 10993-4)	**Pass**	Test articles returned a hemolytic index value that fell within the Non-hemolytic range of <2%.
Hemolysis – Indirect Method (ASTM F756 / ISO 10993-4)	**Pass**	Test articles returned a hemolytic index value that fell within the Non-hemolytic range of <2%.
Hemocompatibility – Complement Activation Assay (ISO 10993-4)	**Pass**	The concentration of SC5b-9 for the test article was not statistically different from the historical controls.
Partial Thromboplastin Time – PTT (ISO 10993-4 / ASTM F2382)	**Pass**	The test article performed better than the comparison article and is considered biologically insignificant.
Blood Platelet and Leukocyte Count Assay (ISO 10993-4)	**Pass**	The test article was not considered to have a significant effect on platelet and leukocyte counts, meeting the test criteria.

STERILIZATION AND SHELF LIFE:

The Primero SAS are sterilized by a traditional Ethylene Oxide gas sterilization cycle. The sterility assurance level (SAL) is 10^{-6}. A sterilization validation for the overall product family of the Primero SAS was completed in accordance with ISO 11135-1:2014.

The Primero SAS are qualified for a one (1) year shelf-life.

CONCLUSION:

The Primero SAS has the same intended use and indications for use, and similar technological characteristics to the Pinnacle Precision Access System and Arrow Nitinol Wire. The differences in technological characteristics between the Primero SAS and the predicate/reference devices were evaluated in bench testing as discussed above and do not raise different questions of safety and effectiveness. Therefore, the results from these tests support the conclusion that the Primero SAS is substantially equivalent to the predicate device.