December 19, 2024

Simpson Interventions, Inc.
Chan Kin
Chief Technology Officer
747 Camden Avenue, Suite E
Campbell, California 95008

Re: K240885
Trade/Device Name: Shadow Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 22, 2024
Received: November 22, 2024

Dear Chan Kin:

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,

Samuel G. Raben -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)*
K240885

Device Name
Shadow Catheter

Indications for Use *(Describe)*
The Shadow Catheter™ is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement and exchange of guidewires and other interventional devices, for use during two guidewire procedures and to subselectively infuse/deliver diagnostic or therapeutic agents.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: December 20, 2024

510(k) Number: K240885

Submitter's Name / Contact Person

Manufacturer
Simpson Interventions
747 Camden Avenue, Suite E
Campbell, CA 95008
U.S.A.

Contact Person
Kin F. Chan, Ph.D.
Simpson Interventions
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General Information

Trade Name	Shadow Catheter™
Common / Usual Name	Catheter, Percutaneous
Classification Name	21 CFR 870.1250, DQY, Percutaneous Catheter, Class II
Predicate Device	K193119, Twin-Pass® Catheter

Device Description

The Shadow Guidewire Positioning Catheter is a dual lumen over-the-wire catheter, compatible with a 6F or larger guiding catheter and 0.014" guidewires. The Catheter is designed to support and aim steerable guidewires. The Catheter consists of a distal tip with markers, torque shaft and guidewire introducer. The distal end of the Catheter (the nosecone) has two ports, one to load a tracking guidewire axially (via distal port) and the other for the positioning guidewire to exit radially (via side port). The distal nosecone is coated with a hydrophilic coating.

The Shadow Catheter™ has three markers in the nosecone. The guidewire introducer accommodates an on-axis tracking guidewire, a tracking guidewire flush port, as well as a positioning guidewire introducer port that doubles as a flush port. The handle may be rotated or orientated to adjust or aim the direction of the positioning guidewire exiting the

side port at the distal end.

The Catheter is placed in a packaging hoop, sealed in a Tyvek® pouch, and packaged in a shelf carton. There are no diagnostic or therapeutic agents known to be incompatible with the Shadow Catheter™. The Shadow Catheter™ is sterilized with ethylene oxide.

Intended Use

The Shadow Catheter™ is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement and exchange of guidewires and other interventional devices, for use during two guidewire procedures and to subselectively infuse/deliver diagnostic or therapeutic agents.

Technological Characteristics Comparison

The different technological characteristics of the subject and predicate devices do not raise different questions of safety and effectiveness. Key similarities and differences in the technological characteristics of the subject and predicate devices include:

Dimensional Attributes
The subject device is a 4F catheter with a uniform outer diameter, while the predicate device is a 3.4F catheter with a larger asymmetrical distal end and a tapered distal tip

Device Compatibility
Both the subject and predicate devices accommodate up to two guidewires. The predicate device has a rapid exchange lumen traversing a small segment of the distal portion of the catheter with the guidewire exiting a distal port, and an “over-the-wire” (OTW) traversing the entire working length of the catheter with the guidewire exiting the side port. The subject device has two lumens that run the entire working length from the proximal end to the distal end of the catheter (OTW) with the tracking guidewire exiting the distal port and the positioning guidewire exiting the side port. Although the guidewire configurations are slightly different, both the subject device and predicate device function similarly.

Hydrophilic Coating
Both the subject and predicate devices contain a hydrophilic coating. The subject device is coated with hydrophilic coating only on the nosecone. It is not known what type of hydrophilic coating is used on the predicate device though it is coated over a longer

working length.

Principles of Operation

Both subject and predicate devices are intended to be used in conjunction with 0.014" guidewires, to access discrete regions of the coronary and peripheral arterial vasculature, in order to facilitate placement and exchange of guidewires and other interventional devices. Both devices are dual lumen in construct, and accommodate up to two guidewires.

Catheter Materials

The subject and predicate devices are both comprised of well characterized, commonly used materials. While the materials used in each catheter are not identical, the subject device has undergone full biocompatibility testing. The markers in the subject device and the markers in the predicate device provide radiopacity and comparable materials are used to enhance visualization under fluoroscopy.

In summary, the different technological characteristics of the subject and predicate devices do not raise new or different questions of safety or effectiveness for the subject device. Similar questions of safety and effectiveness are raised by both devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Compliance with device specific guidance document applicable to product code DQY was followed. Non-clinical testing included the followings: 1) dimensional verification; 2) simulated use; 3) catheter bond strength; 4) tip pull test; 5) flexibility/kink test; 6) torque strength; 7) radiopacity; 8) coating integrity; 9) particulate evaluation; 10) catheter burst; 11) infusion flow rate; and 12) corrosion resistance.

Devices samples passed the following biocompatibility tests performed in accordance with ISO 10993-1:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Mediated pyrogenicity
- Hemocompatibility

- Genotoxicity

Clinical Study: Not Applicable. The Shadow Catheter™ was not evaluated in a clinical study.

Conclusion

The results of the testing met the specified acceptance criteria and did not raise new questions of safety or effectiveness; therefore, the subject device is substantially equivalent to the predicate device.