August 19, 2022

Seven Sons Ltd.
Nancy Zhang
Regulatory Affairs
65 Yigal Alon Street
Tel Aviv, 67443
Israel

Re: K221917
Trade/Device Name: Stent Positioning Assistance System (SPAS)
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: June 17, 2022
Received: June 30, 2022

Dear Nancy Zhang:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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)*
K221917

Device Name
Stent Positioning Assistance System (SPAS)

Indications for Use *(Describe)*
SPAS is an adjunct device intended to be used to maneuver endo-vascular stent delivery systems and support their positioning in Percutaneous Coronary Interventions (PCI). SPAS is not intended for use in neurovascular interventional procedures

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 of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared:	August 15, 2021	
Manufacturer:	Seven Sons Ltd., 65 Yigal Alon Street Tel Aviv, 67443 Israel	
Primary Contact Person:	Vladimir Trapeznikov CEO E-mail: vt@spas-system.com	
Device:	Trade Name:	Stent Positioning Assistance System (SPAS)
	Classification Name:	Catheter Guide Wire
	Classification Regulation:	21CFR 870.1330
	Classification Panel:	Cardiovascular
	Device Class:	Class II
	Primary Product Code:	DQX
Primary Predicate Device:	Trade Name:	Distal Access Torque Device or Controller (Predict or Spinr)
	Manufacturer:	Distal Access, LLC
	510(k) Clearance:	K141054
	Classification Name:	Catheter Guide Wire
	Classification Regulation:	21CFR §870.1330
	Classification Panel:	Cardiovascular
	Device Class:	Class II
	Product Code:	DQX

Device description: SPAS is a sterile disposable device, which serves as adjunct to compatible coronary stent delivery systems. It interfaces with the coronary stent delivery system and supports the positioning the coronary stent on the delivery system.

SPAS is made of biocompatible polycarbonate with an inner polymer sleeve/hub, which interfaces with the distal outer diameter of the catheter of stent delivery systems. It does not interfere with proximal catheter handling until the stent target region is approximated. Then it is slid to the most proximal outer part of the patient's vascular access and fixated with its inner sleeve to the delivery catheter to allow its precise advancement and positioning in the target region.

Indications for Use: SPAS is an adjunct device intended to be used to manoeuvre endo-vascular stent delivery systems and support their positioning in Percutaneous Coronary Interventions (PCI). SPAS is not intended for use in neurovascular interventional procedures.

Technological characteristics: The subject device and the predicates share the same intended use and compatibility with endovascular procedural devices. The subject device and the predicate control the movement of the connected devices by rotatory motions. Both devices share similar technological characteristics (materials, sterilization method, single use and torque ability) as listed detail in below table.

	Proposed Device SPAS	**Predicate Device Distal Access torque device (Predict or Spinr)**
Torque assist provided by	The device can fix/release the coronary stent delivery system and move the fixed delivery system in both forward and backward directions. The delivery system is moved by rotatory motions of the back of the device.	The Distal Access torque device manually rotates devices between 3 and 5 times clockwise and counter clockwise as per the labelled number of rotations. Rotation is manually controlled by the user's finger, thumb and hand.
Sterility	Sterile, ethylene oxide sterilization. Shelf life is defined.	Sterile, ethylene oxide sterilization. Shelf life is defined.

Material	Polycarbonate (body, cap, traveler, retainer) Elastomer (insert)	Medical grade polycarbonate (sleeve, grip, body, screw, slider, and cap components) Stainless steel spring

The SPAS device is substantially equivalent to the predicate devices with regards to its intended use, design function, materials and sterilization method.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the proposed **Stent Positioning Assistance System (SPAS)** and demonstrates compliance with the following FDA recognized consensus standards:

- ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 11135-1:2014, Sterilization of health care products- Ethylene oxide- Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
- ISO 11607-1: 2019, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2: 2019, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ISO 14971: 2019 Medical devices – Application of risk management to medical devices

Non-clinical verification testing has been performed to demonstrate the torque ability, compatibility and usability of the proposed device.

All these tests were used to support substantial equivalence of the subject device and demonstrate that Stent Positioning Assistance System (SPAS)

- complies with the aforementioned international and FDA-recognized consensus standards, and
- meets the acceptance criteria and is adequate for its intended use.

Summary of Clinical Performance Data:	Clinical performance testing has been performed on the proposed **Stent Positioning Assistance System (SPAS)** and included the performance of an usability evaluation of the SPAS device in coronary stenting procedures. The main study objective of this multi-center usability study was to evaluate the usability of the SPAS device in stent positioning. In addition, device-related adverse events and serious adverse events were investigated. The SPAS device was deployed by seven cardiologists in 55 standard stenting procedures. The usability evaluation using a 7-point device usability questionnaire showed that operators were satisfied with the SPAS device. Moreover, no (device-related) adverse events were reported in a wide range of cardiac stenting procedures, from standard to complex.
Substantial Equivalence Conclusion:	The **Stent Positioning Assistance System (SPAS)** is substantially equivalent to the currently marketed predicate device Distal Access Torque Device (K141054) in terms of indications for use, technological characteristic, and safety and effectiveness. Additionally, substantial equivalence was demonstrated by non-clinical performance tests provided in this 510(k) premarket notification. These tests demonstrate that the device complies with the requirements specified in the international and FDA-recognized consensus standards and is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.