July 14, 2023

Embrace Medical Ltd.
℅ Orly Maor
Regulatory Consultant
25 Sirkin Street
Kfar Saba, 4442157
Israel

Re: K223791
Trade/Device Name: TalWire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: June 12, 2023
Received: June 14, 2023

Dear Orly Maor:

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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2023.07.14 12:19:11 -04'00'

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

Indications for Use Statement

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)*

K223791

Device Name

TalWire

Indications for Use *(Describe)*

The TalWire is intended for percutaneous entry of peripheral vessels using the Seldinger Technique. The TalWire is not intended for use in the coronary or cerebral vasculature.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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K223791

Traditional Premarket Notification Submission – 510(k)

Embrace Medical Ltd.- TalWire

Date Prepared: December 14, 2022

I. SUBMITTER

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II. DEVICE

Name of Device: TalWire
Common or Usual Name: TalWire
Classification Name: 21CFR §870.1330- Wire, Guide, Catheter
Regulatory Class: II
Product Code: DQX

III. PREDICATE DEVICE

Embrace Medical Ltd. believes that the Tal Wire is substantially equivalent to the following predicate device:

- Vascular Solutions, Inc., VSI Guidewire, cleared under K112631.

IV. DEVICE DESCRIPTION

The TalWire is a family of vascular access mandrel guidewires. The TalWire is available in various sizes: between 40 to 80 cm in length and in the 0.018" – 0.021" diameter range. The TalWire is available with Nitinol (NiTi) cores and Stainless Steel coils.

The TalWire consist of a solid core shaft with a ground tapered section at the distal end of the guidewire. A micro-coil is wound with a lumen that is then placed over the tapered distal section. The distal end of the coil is secured to the shaft via a weld and the proximal end is bonded to the shaft using adhesive. The TalWire includes an articulatable tip at the distal end of the guidewire.

The finished guidewire is placed in a protective polymer dispenser hoop in a labeled Tyvek pouch. The TalWire is provided as a sterile, single-use device, and is sterilized using a validated ethylene oxide process.

V. INDICATIONS FOR USE

The TalWire is intended for percutaneous entry of peripheral vessels using the Seldinger Technique. The TalWire is not intended for use in the coronary or cerebral vasculature.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The TalWire has the same intended use as the predicate device. Its indications for use are identical to that of the predicate device.

The TalWire has similar technological characteristics as the predicate device as demonstrated in the table below:

Specification	Embrace Medical Ltd. TalWire	Vascular Solutions, Inc., VSI Guidewire	SE Justification
510K Number	K 223791	K112631	
Regulation Number	21CFR §870.1330	21CFR §870.1330	Same
Product Code	DQX	DQX	Same
Classification	Class II	Class II	Same
Indications for Use	The TalWire is intended for percutaneous entry of peripheral vessels using the Seldinger Technique. The TalWire is not intended for use in the coronary or cerebral vasculature.	The VSI Guidewire is indicated for percutaneous entry of peripheral vessels using the Seldinger Technique. The device is not indicated for use in the coronary or cerebral vasculature.	Same
Anatomical Location	Peripheral vessels	Peripheral vessels	Same
Wire Diameter	0.018"-0.021”	0.018”	SE Within the range of cleared guidewires Successful verification testing confirmed the equivalence
Device Length	40-80cm	40cm – 130cm	SE Within the predicate range
Tip Type and Shape	Straight	Straight or Angled	SE Within the predicate range
Wire Mandrel (core) Material	Nitinol	Stainless Steel or Nitinol	SE Within the predicate range
Coating Material, Length and Location	None	None or PTFE coated	SE Within the predicate range
Coil Material	Stainless Steel	Stainless Steel, Tungsten	SE Within the predicate range
Accessories	None	None or may be supplied in a micro-introducer access kit	SE
Packaging configuration	The wire is placed in a protective polymer dispenser hoop in a labeled TyveK pouch. 5 pack configuration	The wire is placed in a protective polymer dispenser hoop in a labeled TyveK pouch. 5 or 10 pack configuration	SE Within the predicate range
Single Use or Reusable	Single Use	Single Use	Same
Sterilization Method	Sterilized by EtO, SAL 10^{-6}	Sterilized by EtO, SAL 10^{-6}	Same

Specification	Embrace Medical Ltd. TalWire	Vascular Solutions, Inc., VSI Guidewire	SE Justification
Biocompatibility	ISO 10993-1	ISO 10993-1	Same

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:
The tests were performed based on *Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling Guidance for Industry and Food and Drug Administration Staff.* Dated: October 10, 2019

- **Biocompatibility**

  Biocompatibility evaluation in compliance with ISO 10993-1 was performed.
  The following tests were conducted:
  Cytotoxicity Study Using the ISO Elution Method
  ISO Guinea Pig Maximization Sensitization Test
  ISO Intracutaneous -irritation Study in Rabbits
  Material Mediated Pyrogenicity in Rabbits
  Acute Systemic Toxicity
  ASTM Hemolysis Study
  SC5b-9 Complement Activation Assay
  Standard Thrombogenicity in Canine
  In addition, chemical characterization and Biological Risk Assessment were performed.
  The device was found biocompatible.

- **Sterilization, Packaging and Shelf Life Testing**

  EtO Sterilization validation was performed. In addition, shelf life and packaging testing were performed to support the labeled shelf life. All tests, including packaging integrity and device performance, were performed after environmental conditioning and transportation simulation.
  All tests were successfully completed.

- **Performance Testing**

  Performance testing per FDA guidance *Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling Guidance for Industry and Food and Drug Administration Staff.* Dated: October 10, 2019
  included the following:

Tests	
• Dimensional Attributes	• Kink resistance
• Visual Inspection	• Tip flexibility
• Simulated use	• Radiopacity
• Tensile strength	• Flex resistance
• Torque strength	• Fracture resistance
• Torqueability	• Prolapse force
• Corrosion resistance	

All tests passed and met the predefined acceptance criteria.

VIII. CONCLUSIONS

The results of the comparison of design, intended use and technological characteristics demonstrate that the device is as safe and effective as the legally marketed predicate device. Therefore, Embrace Medical Ltd. concludes that the proposed TalWire is substantially equivalent to the identified predicate device.