June 29, 2022

Ra Medical Systems, Inc.
Jami Miller
Director of Regulatory Affairs
2070 Las Palmas Drive
Carlsbad, California 92011

Re: K220544
Trade/Device Name: DABRA Excimer Laser System (DABRA Laser model RA-308 and DABRA Catheter model 2.0)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: May 24, 2022
Received: May 26, 2022

Dear Jami Miller:

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

Gregory O'Connell
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)*
K220544

Device Name
DABRA Excimer Laser System (DABRA Laser model RA-308 and DABRA Catheter model 2.0)

Indications for Use *(Describe)*
The DABRA Excimer Laser System is indicated for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease.

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 **K220544**

I Submitter Information

Ra Medical Systems, Inc.

2070 Las Palmas Drive, Carlsbad CA 92011

Company Phone: (760) 804 1648

Fax: (760) 804 1657

Contact: Jami Miller, Director Regulatory Affairs

Date Prepared: June 28, 2022

II Device Identification

Device Trade Name: DABRA Excimer Laser System (DABRA Laser model RA-308 and DABRA Catheter model 2.0)

Common Name: Laser Catheter, Excimer Laser

Classification Name: Percutaneous catheter

Regulatory Class: Class II (per 870.1250 percutaneous catheter)

Device Code: PDU

III Identification of Predicate Device

DABRA Laser System (DABRA Laser Model RA-308 And DABRA Catheter Model 101) (K210664)

Reference Device: CLIRPATH Excimer Laser Catheter (K040067)

IV Device Description

The Ra Medical Systems' DABRA™ Laser Catheter Model 2.0 and RA-308 Excimer Laser is composed of a reusable Excimer laser light source and e-beam sterilized single use catheter.

The laser light is generated by a software-controlled 308nm Excimer source and directed to the catheter through a lens. The fiber and the fluid direct the ultraviolet laser energy from the laser light source to the tip of the catheter. The catheter is connected to the laser for the procedure, and then inserted into the patient's vasculature, allowing the physician to target the laser energy to the lesion.

The laser energy photoablates the lesion creating a lumen that permits blood flow. The lumen can be used for other interventional treatment devices. The system is designed to be used in a catheterization laboratory. This setting includes fluoroscopy devices, injecting devices, patient monitoring devices, a table for the patient, and personnel to assist the physician in performing the treatment.

V Intended Use (807.92(a)(5))

For use in ablating a channel in occlusive peripheral vascular disease.

Indications for Use

The DABRA Excimer Laser System is indicated for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease.

VI Technological Comparison to Predicate Device

The technological characteristics of the subject device are identical to the predicate device in its design, intended use, indications for use, target population, environments for use, fundamental scientific technology, principal of operation and method of action, sterility assurance level (SAL).

	Predicate Device K210664 (DABRA 101)	**Subject Device (DABRA 2.0)**
Intended use	For use in ablating a channel in totally occlusive peripheral vascular disease.	Identical
Indications for use	The DABRA Laser System is indicated for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease.	Identical
Target Population	Patients with Peripheral Artery Disease	Identical
Procedure Site	Catheterization Laboratory	Identical
Technology	308 nm Excimer laser with optical transmitting catheter to lesion Repetition rate 20 to 80 Hz adjustable Energy output 8 mJ minimum Energy density (delivered) across ablation area 7-15 mJ/mm^2 Pulse width 15-120 ns	Identical
Principal of Operation /Mechanism of action	Photoablation	Identical

Catheter provided sterile	Yes	Identical
Sterility Assurance Level of Catheter	10^{-6}	Identical
Single Use Catheter	Yes	Identical
Tip Diameter(s)	1.5 mm	Identical
Working length	150 cm	Identical

The subject device is a modification to the predicate device with the following differences:

Technological Characteristic	**Predicate Device K210664 (DABRA 101)**	**Subject Device (DABRA 2.0)**
Catheter outer jacket	Pebax with polyamide outer jackets	Pebax with stainless steel braid over polyimide/PTFE liner
Length, overall	200 cm	210 cm
Calibration sleeve adhesive	Solvent bond	Cyanoacrylate
Optical fluid	H_2O	Dilute saline
Distal tip and glass length	Tip Length 0.180 Glass Length 7mm	Tip Length 0.139” Glass Length 5mm
Location of marker band	Inside distal tip	Behind distal tip
Strain relief design	Santoprene, 2.1”	Pebax, 4.35”
Sterilization	Gamma irradiation	Electron beam irradiation. Both methods provide a product sterilized to 10^{-6} SAL.
Packaging Design	Proximal end of catheter held in coil with tab on coil card, circular spiral coil, non-barbed plug. Shipper Box contains 12 shelf boxes.	Catheter holder seals the catheter to the packaging coil. Coil is larger in ID and has a larger bend radius. Oblong “racetrack”. Added barbed elbow connector to seal larger coil. Larger shelf box and shipper box. Shipper box contains 8 shelf boxes.
Packaging Materials	Pouch - Mylar	Breathable Tyvek material, larger pouch.
Shelf life	60 Days	6 Months

Software	No warm-up at the beginning of the calibration cycle	Added 15 second warm-up at the beginning of the calibration cycle

VII Performance Data

The following performance data were provided in support of the substantial equivalence determination:

- Length
- Outside Diameter
- Tensile Strength
- Torque Transmission
- Column Strength
- Kink Resistance
- Buckling Force
- Radiopacity
- Insertion/ Retraction Force
- Calibration Sleeve Strength
- Energy Transmission
- Calibration
- Heat Generation
- Corrosion
- Removal From Coil
- Bubble Leak Testing
- Pouch Peel Strength
- Software Testing
- Sterilization Validation

Biocompatibility testing

The DABRA 2.0 catheter was subjected to, and passed, the following biocompatibility testing:

- Cytotoxicity
- ISO Guinea Pig Maximization Sensitization Test
- ISO Intracutaneous Study in Rabbits

- Acute Systemic Toxicity
- Material Mediated Pyrogenicity in Rabbits
- Hemocompatibility: ASTM Hemolysis (Direct and Indirect)
- Hemocompatibility: ASTM Partial Thromboplastin Time
- Hemocompatibility: SC5b-9 Complement Activation Assay
- Hemocompatibility: In Vivo Thromboresistance

VIII Conclusions

The identified differences do not raise new or different concerns of safety or effectiveness relative to the predicate device. Performance testing has demonstrated that the subject device will perform as well as or better than the predicate device. The device has met the applicable design output requirements, demonstrating that the modified device and predicate device are substantially equivalent.