Ra Medical Systems, Inc.
Mr. Dean Irwin
CEO
1930 Kellogg Ave.
Carlsbad, CA 92008

Re: K170349
  Trade/Device Name: DABRA Laser System (DABRA Laser model RA-308 and DABRA Catheter model 101)
  Regulation Number: 21 CFR 870.1250
  Regulation Name: Percutaneous Catheter
  Regulatory Class: Class II
  Product Code: PDU
  Dated: April 24, 2017
  Received: April 24, 2017

Dear Mr. Irwin:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Fernando Aguel -S

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure
Indications for Use

The DABRA 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)
PREMARKET NOTIFICATION

TRADITIONAL 510(k) SUMMARY

Submitter Information

A. Company Name: Ra Medical Systems, Inc.
B. Company address: 1930 Kellogg Ave, Carlsbad CA 92008
C. Company Phone: (760) 804 1648 / (877) 635 1800 Fax: (760) 804 1657
D. Contact Person: Dean Irwin, Chief Executive Officer
E. Date Prepared: January 20, 2017

Device Identification

A. Device Trade Name: DABRA Laser System (DABRA Laser model RA-308 and DABRA Catheter model 101)
B. Device Common Name: Laser Catheter, Excimer Laser
C. Classification Name: Percutaneous catheter
D. Device Class: Class II (per 870.1250 percutaneous catheter)
E. Device Code: PDU

Identification of Predicate Device

Spectranetics CLiRpath Laser Catheters; K040067.

Identification of Reference Devices

Ra Medical EX-308; K062963
Spectranetics CVX-300; K052514

Device Description

Ra Medical Systems is requesting FDA 510(k) clearance for the DABRA Laser (model RA-308) and DABRA™ Catheter (model 101) as a system, collectively the DABRA Laser System™.

The Ra Medical Systems’ DABRA Laser System™ is composed of a laser light source and catheter consisting of optically conducting fluid encased in medical grade tubing enclosed by an optical window on either end. The tip and the fluid conduct the ultraviolet laser energy from the laser light source to the distal tip of the catheter. The laser light is generated by a 308nm excimer source. 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 a blockage or lesion. Patient contacting parts of the device are the distal tip (titanium), the distal tip window (glass), the glue for the distal tip (epoxy), and the catheter tube (FEP). These parts are limited (<24 hours) blood contact. The laser energy photoablates the lesion material creating a lumen that permits blood flow, and allows access for other interventional treatment devices, such as balloons. The system is designed to be used in a catheterization laboratory. The candidates for this type of laser treatment are people who have blockages in their leg arteries that completely obstruct flow (chronic total occlusions). Flow obstruction of this type causes pain, wounds that do not heal, gangrene and ultimately limb amputation.
**Intended Use (807.92(a)(5))**

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

**Indications for Use**

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

**Comparison to Predicate Devices**

The DABRA Laser™ and DABRA Catheter™ use the same materials (plastics, glass, metal), the same light source and energy (308nm excimer at 15mJ), the same constructions, and the same interventional techniques (step-by-step) to operate as the predicate device. The differences between the devices include a more compact excimer source and an optically conducting material as opposed to a continuous glass element. The materials that define the laser output as well as the materials that contact the patient are all either identical, or are substantially equivalent in regards to the interaction of the device with the patient or the operator. The DABRA Catheter™ is 1.5mm in diameter whereas the predicate device is for a line of different sized catheters ranging from .9mm to 2.5mm. The device that is closest in diameter is the CLiRpath 1.4mm device, which was the subject of comparison bench tests. The DABRA Catheter™ has a working length of 150cm.

The RA-308 light source for the device is nearly identical to the EX-308, with different delivery device connections and software. The RA-308 Laser is identical to the EX-308 in fit, form, function, energy type, materials, and use.

The Spectranetics CVX-300 reference device also has an 80Hz repetition rate and continuous operation.

The DABRA Laser™ and DABRA Catheter™ were bench tested using a wide variety of protocols. These protocols also included side-by-side performance tests. The direct comparison tests included:

a. Energy output
b. Output fluence in mJ/mm² applied to the target
c. Beam divergence and beam profile
d. Energy transmission in test models
e. Ablation though non-biological samples to demonstrate hole size and features
f. Ablation through biological materials (in vitro porcine)
g. Vasculature maneuverability in test models
h. Insertion and retraction force, at time of manufacture and aged 2 years

Other bench tests on sterilized catheters (where applicable) include:

a. Pull testing, at time of manufacture and aged 2 years
b. Corrosion resistance
c. Patent artery perforation testing
d. Kink testing, at time of manufacture and aged 2 years
e. Torque testing, at time of manufacture and aged 2 years
f. Radio opaque tip testing
g. Catheter fluid leak analysis
h. Package integrity validation
i. Process indicator validation
j. Dimensional testing, at time of manufacture and aged 2 years
k. Particulate investigation
l. Simulated use testing

Other testing to show conformance to various standards include:

- IEC 60601-1 Electrical safety
- IEC 60825-1 Safety of laser products
- IEC 60601-2-22 Basic safety and essential performance of laser equipment
- IEC 60601-1-2 Electromagnetic compatibility
- 21 CFR 1010 and 1040 Electronic products and light-emitting products
- ISO 10555 Sterile single-use intravascular catheters
- IEC 62366 Usability engineering

**Biocompatibility and Sterilization**

The Ra Medical DABRA Catheters™ are manufactured from materials and components that are commonly used in other catheters already marketed. All of the materials conform to ISO 10993, Biological Evaluation of Medical Devices. The following biocompatibility testing has been performed:

- C3a complement activation
- Cytotoxicity
- Guinea pig maximization sensitization
- Direct and indirect hemolysis
- Intracutaneous reactivity
- Partial thromboplastin time
- Material-mediated Pyrogenicity
- SC5b-9 complement activation
- Acute systemic toxicity
- In vivo human thrombus evaluation

Ra Medical conducts and maintains valid gamma radiation sterilization processes in conformance with ISO 11137 Sterilization of Health Care Products – Radiation. The packaging for the DABRA Catheters™ has been initially validated, and each is visually inspected prior to delivery to finished goods. A shelf life of 1 year was validated based on successful packaging integrity and product performance testing using accelerated aged and real time aged device samples.
Each catheter is inspected and 100% tested for dimensions and functionality. It has been validated for integrity to conform to ISO 10555-1 Sterile Single-Use Intravascular Catheters.

Clinical Results

The device was used on 50 patients (66 lesions) in two studies to determine that the device is substantially equivalent to the predicate in terms of procedure outcome, adverse events, and physician use. The performance goal was exceeded.

a. the device deployed properly and predictably from the packaging,
b. the device navigated the vasculature easily,
c. the device crossed the lesions with the predicted manner, time and ease,
d. the outcome of the procedure was as predicted,
e. the follow-up on the patients revealed no undesired effects,
f. there were no observed adverse events or safety issues according to the study protocol.

Conclusion

The analysis, testing, and clinical study establish the substantial equivalence between the Ra Medical Systems DABRA Laser™ and DABRA Catheter™ and the predicate device, and demonstrate that the device performs equivalently to the referenced predicate and exceeded the performance goal.