DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 23, 2017

Dutch Ophthalmic Research Center International BV
Ms. Linda van Leeuwen
Manager Regulatory Affairs
Scheijdelveweg 2
Zuidland, 3214 VN
The Netherlands

Re: K160591
Trade/Device Name: D.O.R.C. Disposable Cryo Probe
Regulation Number: 21 CFR 886.4170
Regulation Name: Cryophthalmic Unit
Regulatory Class: Class II
Product Code: HRN
Dated: November 29, 2016
Received: December 21, 2016

Dear Ms. van Leeuwen:

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 yours,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological H

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160591

Device Name
D.O.R.C. Disposable Cryo Probe

Indications for Use *(Describe)*
The D.O.R.C. Disposable Cryo Probe is intended for use in combination with the Cryostar Cryosurgical System to perform ophthalmic surgery of the posterior or anterior segments including cryopexy for retinal detachment, glaucoma, cataract extraction, trichiasis, and retionopathy of prematurity.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

This summary is in accordance with 21 CFR 807.92.

Submitter

The submitter of the 510(k) is:

D.O.R.C. Dutch Ophthalmic Research Center (International) B.V.
Scheijdelveweg 2
3214 VN Zuidland
The Netherlands

Contact person: Mrs. Daniëlle Sleegers, Manager Regulatory Affairs
Phone: +31 181 458080
Email: RAUSA&Canada@dorc.eu

Date Prepared: January 20th, 2017

Device

Device Subject to this 510(k):

Trade Name:	D.O.R.C. Disposable Cryo Probe
Common Name:	Cryophthalmic Probe
Classification:	II
Classification Name:	Cryophthalmic unit (21 CFR 886.4170, Product Code HRN)

The following regulations are applicable for this 510(k):

- 21 CFR 886.4170 Cryophthalmic unit

Predicate Devices

510(k) Number	Device
K012821	Cryostar Cryosurgical System Reusable Cryo Probe (D.O.R.C.)
K131787	Cryomatic Disposable Cryo Probes (Keeler Ltd.)

Device Description

The D.O.R.C. Disposable Cryo Probe is a single-use, handheld medical device intended for use in combination with the Cryostar Cryosurgical System to perform ophthalmic surgery. When the foot pedal of the CryoStar Console is pressed, high pressure gas (CO_2 or N_2O) is supplied via a small aperture to target tissue.

Indications for Use

The D.O.R.C. Disposable Cryo Probe is intended for use in combination with the Cryostar Cryosurgical System to perform ophthalmic surgery of the posterior or anterior segments including cryopexy for retinal detachment, glaucoma, cataract extraction, trichiasis, and retionopathy of prematurity.

Comparison of Technological Characteristics with the Predicate Devices

There are no technological characteristics or features of the D.O.R.C. Disposable Cryo Probe that have not been previously cleared in predicate devices as is shown in the following table.

Comparison of Features of the D.O.R.C. Disposable Cryo Probe and Predicate Devices

Description	Proposed Device - Disposable Cryo Probe (D.O.R.C.)	Cryostar Cryosurgical System Reusable Cryo Probe (D.O.R.C.)	Cryomatic Disposable Cryo Probes (Keeler Ltd.)
510(k) #	K160591	K012821	K131787
Product Code(s)	HRN	HRN	HRN
Intended Uses	Cryophthalmic surgery	Cryophthalmic surgery	Cryophthalmic surgery
Cryogen Gas Delivered	Nitrous Oxide and Carbon Dioxide	Nitrous Oxide and Carbon Dioxide	Nitrous Oxide and Carbon Dioxide
Method of Operation	Rapid expansion of cryogenic gas causes a freezing effect according to the Joule-Thompson principle	Rapid expansion of cryogenic gas causes a freezing effect according to the Joule-Thompson principle	Rapid expansion of cryogenic gas causes a freezing effect according to the Joule-Thompson principle
Freeze Rate	After 10s operation an ice ball diameter shall be at least 4mm when immersed 2mm in water of 20°C with both CO_2 and N_2O	After 10s operation an ice ball diameter shall be at least 4mm when immersed 2mm in water of 20°C with both CO_2 and N_2O	Unknown
Defrost Rate	Within 5s the ice ball of at least 4mm shall be released when defrost function is activated with both CO_2 and N_2O	Within 5s the ice ball of at least 4mm shall be released when defrost function is activated with both CO_2 and N_2O	Unknown
Compatible with System	Cryostar 1500.III (K012821)	Cryostar 1500.III (K012821)	Cryomatic MKII (K131787)
Control Mechanism	Footswitch of Cryostar	Footswitch of Cryostar	Footswitch of Cryomatic MKII
Single Use	Yes	No (Reusable)	Yes
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Tip Material	Stainless Steel	Stainless Steel	Stainless Steel
Handle Material	Acetal	Aluminum	Metal (Unknown)
Supply Tube	Stainless Steel	Flexible plastic	High-pressure plastic
Exhaust Tube	Flexible Nylon	Flexible plastic	Unknown
Tip Outer Diameter, Geometry	2.5 mm, angled	2.5 mm, angled	Unknown
Length (Handpiece and Tip)	5.4 inches (136,3 mm)	5.9 inches (150 mm)	Unknown
Total Weight	58 grams	328 grams	Unknown
Packaging	Peel Pouch	Peel Pouch	

Performance Data

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

Biocompatibility testing

The biocompatibility evaluation of the D.O.R.C. Disposable Cryo Probe was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

Performance Testing

Although animal and clinical performance testing was not required for the D.O.R.C. Disposable Cryo Probe to demonstrate efficacy, safety and substantial equivalence to predicate devices, a variety of laboratory (bench) performance tests have been conducted including freeze and defrost performance and compatibility testing with the Cryostar 1500.III Cryosurgical System. The 'freeze performance' test showed that both the Disposable Cryo Probe (1540.D) and the Reusable Cryoprobe (1540) produced an ice ball of on average 4.9mm after 10s operation when immersed in water of 20°C with both CO_2 and N_2O. The 'defrost performance' test showed that both the Disposable Cryo Probe (1540.D) and the Reusable Cryoprobe (1540) released the ice ball of at least 4mm within 5s after activation of the defrost function with both CO_2 and N_2O. Therefore it was concluded that the Disposable Cryoprobe (1540.D) is equivalent to the Reusable Cryoprobe (1540). Both the 'freeze performance' test and the 'defrost performance' test were performed using the Cryostar (1500.III), showing the compatibility of the Disposable Cryoprobe (1540.D) with this Cryosurgical System.

The device will comply with applicable sections of the following standards:

Standard #	***Title***
EN ISO 10993-1:2009/AC:2010	Biological Evaluation Of Medical Devices -- Part 1: Evaluation And Testing
EN ISO 10993-5: 2009	Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
EN ISO 10993-7: 2008/AC:2009	Biological Evaluation Of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
EN ISO 10993-10: 2010	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Sensitization
ISO 10993-12: 2012	Biological Evaluation Of Medical Devices - Part 12: Sample Preparation and Reference Materials
ISO 11135-1:2007	Sterilization Of Health-Care Products - Ethylene Oxide – Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN ISO 14971:2012	Medical Devices: Application Of Risk Management To Medical Devices
ISO 11607-1:2009	Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems
ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
ISO 15223-1:2012	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ASTM D4169-14	Practice for performance testing of shipping containers and systems Practice for performance testing of shipping containers and systems
EN 62366:2008	Medical devices - Application of usability engineering to medical devices

Conclusion

The information presented in this 510(k) premarket notification demonstrates that the D.O.R.C. Disposable Cryo Probe is substantially equivalent to the legally marketed predicate devices.