DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 29, 2016

Air Liquide Healthcare America Corporation
% Michael Hinckle
Partner
K&l Gates LLP
430 Davis Drive, Suite 400
Morrisville, North Carolina 27560

Re: K153564
Trade/Device Name: Pure Cryogen
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: February 23, 2016
Received: February 24, 2016

Dear Michael Hinckle:

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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153564

Device Name
Pure Cryogen

Indications for Use *(Describe)*
PURE CRYOGEN is indicated to be used as an accessory to Candela Corporation's Dynamic Cooling Device as a source of skin refrigerant fluid. The intended use of PURE CRYOGEN is (1) cooling of the skin prior to laser treatment, (2) reduction of pain during laser treatment, (3) allows for use of higher laser fluences for laser treatments, such as for hair removal and vascular lesions, and (4) reduces potential side effects of laser treatments, such as for hair removal and vascular lesions.

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

The following summary is provided in accordance with 21 CFR 807.92:

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Date Prepared: December 11, 2015

B. NAME/ADDRESS OF SPONSOR

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C. DEVICE

Trade Name of Device: PURE CRYOGEN
Common or Usual Name: Skin Refrigerant
Classification: Class II
Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)
Product Code GEX

D. PREDICATE DEVICE

Candela Dynamic Cooling Device™ (K001589)

E. DEVICE DESCRIPTION

Air Liquide's PURE CRYOGEN consists of a disposable, non-refillable cylinder containing 1,1,1,2-Tetrafluoroethane, commonly referred to as HFC-134a Low NAG gas ("134a gas"). The 134a gas cylinder is intended to be used as an accessory to Candela Corporation's Dynamic Cooling Device™ as a source of skin refrigerant fluid. The cylinder may be inserted into the Dynamic Cooling Device, which is then connected in line with Candela's laser device. Candela's laser controls the delivery of a pulsed spray of 134a gas just prior to the delivery of a laser pulse. The pulsed spray of skin refrigerant cools the skin as it evaporates. Use of the 134a gas prior to laser treatment minimizes thermal damage to skin during laser treatment and reduces pain associated with laser treatment.

F. INTENDED USE / INDICATIONS FOR USE

The PURE CRYOGEN is indicated to be used as an accessory to Candela Corporation's Dynamic Cooling Device as a source of skin refrigerant fluid. The intended use for PURE CRYOGEN is: (1) cooling of the skin prior to laser treatment, (2) reduction of pain during laser treatment, (3) allows for use of higher laser fluences for laser treatments, such as for hair removal and vascular lesions, and (4) reduces potential side effects of laser treatments, such as for hair removal and vascular lesions.

G. TECHNOLOGICAL CHARACTERISTICS

The PURE CRYOGEN device and the predicate device share the same technological characteristics. Both devices consist of a non-refillable, disposable steel cylinder of identical dimensions containing 1,000 grams of a refrigerant with the chemical compound 1,1,1,2-tetrafluoroethane (commonly referred to as HFC-134a Low NAG Grade gas ("134a gas")) filled to an internal pressure of 81.9 pounds per square inch gage (PSIG). The cylinder of both the PURE CRYOGEN device and the predicate device is designed to be inserted into a Candela Corporation Dynamic Cooling Device (DCD) for use as a skin refrigerant fluid during laser procedures with a DCD-compatible laser system. Both devices connect to a DCD device using a connector/valve combination with the same design and construction.

H. NON-CLINICAL PERFORMANCE DATA

Non-clinical performance testing was completed to demonstrate the substantial equivalence of the PURE CRYOGEN device and the predicate device and to confirm the labeled shelf-life of the device. A study was conducted to confirm that the PURE CRYOGEN device could be used in the parent DCD device in the same manner as the predicate device and without the need for any modification of the DCD. The study consisted of: (a) a comparison of the cylinder height, diameter, valve threads, and compatibility with the DCD's cylinder engagement mechanism; and (b) multiple manual comparative insertions of the PURE CRYOGEN and predicate devices into a DCD device. Additionally, a leak rate test was conducted to determine the total gas leakage from the PURE CRYOGEN cylinder after five years in order to support the labeled shelf-life of the device.

I. CONCLUSIONS

The PURE CRYOGEN device and the predicate device possess the same intended uses, indications for use, technological characteristics, and principles of operation. Data from performance testing confirmed that the PURE CRYOGEN device is a compatible accessory to the DCD and does not raise any new issues of safety or effectiveness as compared to the predicate device. Thus, the PURE CRYOGEN is substantially equivalent to the predicate device.