DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 23, 2016

H&O Equipments, nv/sa
% Ms. Patsy Trisler
Qserve Group US, Inc.
5600 Wisconsin Avenue, #509
Chevy Chase, MD 20815

Re: K161615
Trade/Device Name: Accurett ®
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: August 2, 2016
Received: August 3, 2016

Dear Ms. Trisler:

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,

Christopher J. Ronk -S

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)*
K161615

Device Name

Accurett®

Indications for Use *(Describe)*

To destroy tissue during surgical procedures by applying extreme cold.

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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510(k) SUMMARY— Accurett®

K161615

I. SUBMITTER	
Submitter Name:	H&O Equipments nv/sa
Submitter Address:	Rue des Journaliers 1 7822 Ghislenghien BELGUIM
Contact Person: **Telephone #:**	Aline Frank, Quality Manager +32 68 26 86 00
US Contact:	Patsy Trisler, Regulatory Consultant, Qserve Group US 301.652.5344
Date Prepared:	7 June 2016
II. DEVICE	
Device Trade Name:	Accurett®
Common and Classification Name(s):	Cryosurgical Unit and Accessories
Classification #:	21 CFR 878.4350
Product Code	GEH
Regulatory Class	2
Review Panel	General and Plastic Surgery
III. PREDICATE DEVICE	K024009, CryoProbe™
IV. DEVICE DESCRIPTION	
	The Accurett® is a hand-held cryosurgical instrument for destroying tissue during surgical procedures by applying extreme cold gas, carbon dioxide (CO_2). The device design is based on direct application of carbon dioxide in the liquid phase to the selected area. The CO_2 gas is delivered to the treatment site at -79ºC to effect cellular destruction.
	The hand-held device is shaped like a pencil to afford maximum user comfort. Prior to use, a commercially available 16g CO_2 gas cylinder cartridge is loaded into the Accurett® device. The flow of gas is controlled by a trigger on the unit.
	Mode of operation: Joule-Thompson Principle to cool the gas.
DESCRIPTION OF DEVICE MODIFICATIONS	The only modification to the marketed predicate CryoProbe is the cryogen source, from N_2O gas to CO_2 gas.

V. INDICATIONS FOR USE	To destroy tissue during surgical procedures by applying extreme cold.
VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES	The Accurett® has the same intended use as the predicate and reference devices. There are no technological differences between the marketed CryoProbe predicate and the Accurett®. The only modification, as noted, is the use of the alternative cryogen, CO_2 gas. To address this difference, performance testing was provided. The Accurett® and the predicate have the same mode of operation: Joule-Thompson. The result of use of the different gas is the output temperature: for the CO_2 it is -79ºC while for the N_2O it is -89ºC.
VI. SUMMARY OF PERFORMANCE DATA AND DESIGN CONTROLS	A Risk Analysis was performed according to ISO 14971:2012 and documentation was included in the 510(k) to assess the impact of the change of cryogenic gases. As a result, design verification testing was performed to assure the use of the CO_2 gas was appropriate, safe and effective for the intended use.
VIII. CONCLUSION OF SUBSTANTIAL EQUIVALENCE	The information and data provided in this Special 510(k) establish that H&O Equipment's modified cryosurgical instrument, the Accurett®, is substantially equivalent in the intended use, design, principle of operation, technology, materials, specifications and performance to the CryoProbe predicate.