DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 2, 2017

ISOVAC Products, LLC
% Jeffery Jones
Consultant
JL Jones Group, Inc
1213 Kevington Drive
Antioch, Illinois 60002

Re: K163223
Trade/Device Name: ORCA™ - Operational Rescue Containment Apparatus
Regulation Number: 21 CFR 880.5450
Regulation Name: Patient Care Reverse Isolation Chamber
Regulatory Class: Class II
Product Code: LGN
Dated: September 29, 2017
Received: October 4, 2017

Dear Jeffery Jones:

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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K163223

Device Name
ORCA (tm) - Operational Rescue Containment Apparatus

Indications for Use *(Describe)*
The Model ORCA-2016CN is a portable and ambulatory Patient Isolation Unit (PIU) designed to prevent chemical and particulate (biological and radiological) cross-contamination between an enclosed contaminated patient and the external environment during evacuation and transport activities.

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.

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510(k) Summary

Submitter's Name: ISOVAC Products, LLC
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Contact person: Mr. Jeffery Jones, Consultant

Date of Summary: October 31, 2017

Device Names:

Trade Name: ORCA™ - Operational Rescue Containment Apparatus

Common Name: Patient Isolation Unit (PIU)

Regulation Name: Patient care reverse isolation chamber

Classification Name: Class II (21 CFR 880.5450)
Product Code: LGN

Predicate Device:

The legally marketed predicate device is the CAPSULS Patient Isolation Unit (K052798) manufactured by ISOVAC Products. -

Device Description:

The Operational Rescue Containment Apparatus (ORCA™) Patient Isolation Unit, Model ORCA-2016CN, is a tubular, flexible, Patient Isolation Unit (PIU) for use during transport and evacuation of chemical and particulate (biological and radiological) contaminated patients who have been medically stabilized. Each unit employs clear windows to allow visual monitoring of the patient. The unit incorporates multiple glove arms for minimal medical intervention.

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The PIU's have a reinforced base mat with integrated carry straps and tethers to enable lifting and attachment to a Stokes litter for hoisting operations or a North Atlantic Treaty Organization (NATO) litter for alternative transportation. Chamber airflow through the isolator and across the patient is provided by the blower from a Powered Air-Purifying Respirator (PAPR). Internal contaminated air in the PIU is vented out the exhaust ports which are fitted with two Chemical, Biological, Radiological, Nuclear (CBRN) filter cartridges, thus protecting the external environment from a contaminated patient.

The device is used by trained medical personnel, who may or may not be licensed physicians or surgeons, and who may or may not be operating the device under the supervision of such licensed medical professionals. For this reason, ISOVAC Products intends that the ORCA™ be cleared for over-the-counter use.

Indications for Use:

The Model ORCA-2016CN is a portable and ambulatory Patient Isolation Unit (PIU) designed to prevent chemical and particulate (biological and radiological) cross-contamination between an enclosed contaminated patient and the external environment during evacuation and transport activities.

Descriptive Summary of Technological Characteristics:

The indications for use and principles of operation of the ORCA™ Patient Isolation Unit are essentially identical to those of the predicate device (CAPSULS™); however, the ORCA™ device will additionally protect the external environment from a chemically contaminated patient. The unit is lighter in weight, and provides first responders with hoisting capability. Differences between the devices result primarily from technological advances, such as those in materials technology, which have occurred since the CAPSULS™ device was introduced in 2005.

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Differences between the predicate and proposed devices are shown in **BOLD** type.		
PARAMETERS	**PREDICATE DEVICE**	**PROPOSED DEVICE**
INTENDED USE	The CAPSULS (Containment and Protection System Utilizing Life Support) is a portable Patient Isolation Unit (PIU) It is intended for the transport of patients while preventing particulate (biological and radiological) cross-contamination between the patient and the external environment. PIU is designed with features that enable medical intervention.	The Model ORCA-2016CN (Operational Rescue Containment Apparatus) is a portable and ambulatory Patient Isolation Unit (PIU) The Model ORCA-2016CN is a portable and ambulatory Patient Isolation Unit (PIU) designed to prevent chemical and particulate (biological and radiological) cross-contamination between an enclosed contaminated patient and the external environment during evacuation and transport activities.
FRAMEWORK	Plastic resin stanchions and integral ribs	Plastic rib structure
ENVELOPE	Zippered transparent flexible PVC or Polyurethane (PUR) welded transparent film enclosure	**Zippered GORE® CHEMPAK® SPM Fabric enveloped with** clear PVC viewing windows
LIFTING AND TRANSPORT SUPPORT	The CAPSULS is intended for mounting on a standard medical litter that can also be lifted by a (PVC or PUR) coated fabric mesh base mat	The ORCA is intended for mounting on a standard medical litter **or on a Stokes litter (not supplied) during hoisting operations** that be lifted by a

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	with carry straps integral to the product.	**fabric mesh base mat** with carry straps integral to the product.
AIR SUPPLY BLOWER	C420, battery operated, military issue, commercial (Powered Air Purifying Respirator) blower	C420, battery operated, military issue, commercial (Powered Air Purifying Respirator) blower.
BLOWER POWER SUPPLY AND CONTROLS	One replaceable or rechargeable, 10-hour, 6VDC battery. Blower incorporates ON/OFF switch Low battery alarm	6VDC battery options: #1: D-Cell battery pack (standard) #2: AA-Cell battery pack #3: Rechargeable NiMH battery #4: BA5800/U $LiSO_2$ Blower incorporates ON/OFF switch Low battery alarm
AIR FILTRATION	Two (2) M95, P100/HEPA (High Efficiency Particulate Air) rated filter cartridges	Two (2) M96, P100/HEPA (High Efficiency Particulate Air) rated filter cartridges
ROUGHING FILTERS	Integral with the M95 cartridges described above.	Integral with the M96 cartridges described above.
AIR FLOW CONTROL	Airflow from patient head to foot is set by the blower manufacturer at 4 CFM. Air backflow is prevented by check valves.	Airflow enters at the rights side of patient head and is exhausted to the left of patient head. Airflow rate is set by the blower manufacturer at 4 CFM. Air backflow is prevented by a check valve.
PATIENT ANCILLARY OXYGEN	Tubing ports compatible with oxygen tubing and mask (not supplied)	**No Tubing Ports**
LIFTING HANDLES	CAPSULS™ is designed to be mounted on and lifted with the handles of a standard medical litter. In the absence of a litter, CAPSULS may be lifted with the	ORCA is designed to be mounted on and lifted with the handles of a standard medical litter or NATO or Stokes litter. In the absence of a litter, ORCA may be lifted with the

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	four integral carrying straps on each side of the unit.	four integral carrying straps on each side of the unit.
ABSORBENT PAD	No Absorbent Pad	**Internal Absorbent Pad**
AIR CHANGES	15-20 air changes per hour under normal use conditions.	**20-38 air changes per hour** under normal use conditions.
DIMENSIONS (with handles retracted)		
Length	78" envelope, 88" overall length with blower and stanchions	**81" overall length**
Width	24 inches	**26 inches**
Height	18 inches	**20 inches**
Storage Height	15 inches	**10 inches**
Storage Volume	Approximately 3 cubic feet	**Approximately 4.2 cubic feet**
Weight	25 lbs. (polyurethane), 35 lbs. (PVC)	**21 lbs.**

Performance Data:

Operation system testing was successfully conducted on the ORCA™ PIU by the U.S. Coast Guard. This operational testing included hoisting and transport of the PIU with the test platform being a MH-60 helicopter. The PIU was hoisted multiple times at various altitudes (25/50/75/100 ft.) using a trail line to stabilize the stokes litter (video documentation is on file with the USCG). The results from this performance testing, to the satisfaction of the USCG, validated the "proof of concept" for using the PIU in USCG aircraft. The MH-60 generates 90 plus knots of downward rotor wash during a hover and this was deemed by the

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USCG as sufficient testing as the PIU is intended to be a one time use piece of equipment. USCG Tactics, Techniques and Procedures (TTP) for operational use of the PIU clearly articulates this requirement/limitation of the PIU. This includes the maximum flight duration allowed, DECON, training and maintenance. While a small boat could be used for transport of the PIU, the current CONOP uses a helicopter as this is the most extreme condition and most likely in the event we are transporting a contaminated patient.

The predicate device was not designed for hoisting.

Performance system testing was successfully conducted on the ORCA™ PIU by a third-party testing party under contract with the USGC. This performance testing included Chemical Agent Permeation (HD (distilled mustard) and GD (soman)), Liquid Penetration / Pathogen Passage, Human Use Comfort, and Weight Lift Testing.

PIU system permeation testing was performed in principle to those methods described in Institute of Environmental Sciences and Technology IEST- RP-CC001.3 (Ref 2) and MIL-STD-282 Method 102.9.1 (Ref 3) and demonstrated a containment efficiency (%) for both aerosols at a maximum 0.3 micron particle size exceeded the objective requirement. Liquid Penetration / Pathogen Passage testing was performed using methods described in ASTM F1671/F1671M-13: *Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System*. No detectable bacteriophage in the assay titer (i.e., 0 PFU/mL) was considered passing. The Bag Seam, Sleeve Seam, and Window Seam three materials passed liquid penetration testing.

Human interface comfort testing was performed using a test participant (TP) while being contained in the PIU for four hours. The participant was exposed to a matrix of six (6) temperature and RH% environments ranging from 65-90ºF and 40 - 90% in a wind speed of 4 mph. Internal PIU temperature, RH%, CO_2 and O_2 levels, as well patient vitals and comfort levels were monitored over the four-hour test duration. The TP's vital signs were stable for the duration of the test with no indication of any heat stress or health related issue. Additionally, the TP reported no significant problems throughout the duration of the test.

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The PIU weight lift capacity was tested under ISOVAC standard protocol procedure. The testing demonstrated the PIU handle strapping can hold the maximum test load of 480lb or a load of 137% of the stated maximum.

Conclusion:

The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified as the CAPSUL Patient Isolation Unit, cleared under the 510(k) submission number K052798.