January 3, 2024

Carecubes, Inc.
Steve Bollinger
Operational Lead
300 Oxford Drive
Suite 330
Monroeville, Pennsylvania 15146

Re: K231256
Trade/Device Name: Carecube Negative Pressure Isolation Chamber
Regulation Number: 21 CFR 880.5450
Regulation Name: Patient Care Reverse Isolation Chamber
Regulatory Class: Class II
Product Code: LGM
Dated: April 27, 2023
Received: May 1, 2023

Dear Steve Bollinger:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices

OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231256

Device Name
Carecube Negative Pressure Isolation Chamber

Indications for Use *(Describe)*
The Carecube is a patient isolation unit (PIU) designed for the temporary isolation of patients within a hospital setting to prevent particulate (biological) cross-contamination between user and patient, while enclosing the contaminated patient from the external environment. Device should only be used in a hospital setting. This is for temporary housing of a patient prior to transfer to an appropriate hospital destination. Transfer to a more permanent hospital setting should occur as soon as possible. The Carecube is designed with features that enable low-moderate complexity medical interventions. This includes the following procedures: blood draw, medication administration, palpating abdomen, cardiac auscultation, and connection to IV line/monitoring cables.

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
K231256
Carecube Negative Pressure Isolation Chamber

I. Submitter Information

Carecubes, Inc.
3101 20th Street
San Francisco, CA 94110

Contact Person:	Steve Bollinger
Telephone Number:	(508) 942-6396
Email:	steve@carecubes.com
Date Prepared:	January 03, 2023

II. Device

Trade Name:	Carecube Negative Pressure Isolation Chamber
Common Name:	Patient Isolation Unit (PIU)
Classification Name:	Chamber, Patient Isolation
Produce Classification:	Class II
Regulation Number:	21 CFR 880.5450
Product Code:	LGM

III. Predicate Device:

Predicate Device Name	510(k)	Company Name
CAPSULS™ Patient Isolation Unit	K052798	ISOVAC Products, LLC
Reference Device		
ORCA™ Operational Rescue Containment Apparatus	K163223	ISOVAC Products, LLC

IV. Description of Device:

The Carecube Negative Pressure Isolation Chamber is a modular, negative pressure, isolation patient care system with both reusable and disposable components that can rapidly augment capacity to care for airborne infectious diseases and other biological threats for common patient care protocols with features built into the unit to allow ease of execution. The device is intended to be used indoors, in a hospital setting, as a temporary isolation of patients with suspected or confirmed diagnosis of infectious disease to prevent Healthcare Practitioners (HCP) exposure to pathogenic biological airborne particulates and is designed with features that enable low-moderate complexity medical interventions.

V. Intended Use:

The Carecube Negative Pressure Isolation Chamber is a patient isolation unit (PIU) intended to be use in hospitals as a negative pressure isolation chamber. The Carecube is intended to be used by a single patient for up to 24 hours of continuous use. The Carecube Negative Pressure Isolation Chamber Canopy is intended for multi-patient use with a maximum of ten (10) patients. The Arm Access, Auxiliary Arm Access and Trunk ports of the Carecube Negative Pressure Isolation Chamber are intended for single-patient use only. The unit is designed to be used with the required personal protective equipment (PPE).

VI. Indications for Use:

The Carecube is a patient isolation unit (PIU) designed for the temporary isolation of patients within a hospital setting to prevent particulate (biological) cross-contamination between user and patient, while enclosing the contaminated patient from the external environment. Device should only be used in a hospital setting. This is for temporary housing of a patient prior to transfer to an appropriate hospital destination. Transfer to a more permanent hospital setting should occur as soon as possible. The Carecube is designed with features that enable low-moderate complexity medical interventions. This includes the following procedures: blood draw, medication administration, palpating abdomen, cardiac auscultation, and connection to IV line/monitoring cables.

VII. Comparison of Technological Characteristics with Predicate Devices

The indications for use and principle of operation of the Carecube Negative Pressure Isolation Chamber are equivalent to those of the predicate device, ISOVAC CAPSULS™ Patient Isolation Unit (K052798) and reference device, ISOVAC ORCA™ Operational Rescue Containment Apparatus (K163223). Differences between the devices result primarily from technological advances which have occurred since the ISOVAC CAPSULS™ device was introduced in 2005.

Table 5-1. General Technological Characteristics Comparison

PARAMETER	PROPOSED DEVICE	PREDICATE DEVICE	COMPARISON
Trade Name	**Carecube Negative Pressure Isolation Chamber**	**CAPSULS™ Patient Isolation Unit**	
Manufacturer	Carecubes, Inc.	ISOVAC	
510(k)	K231256	K052798	
Product Classification	II	II	Same
Product Code	LGM	LGN	Equivalent Carecube (LGM) is not used for transport (LGN)
Regulation Number	880.5450	880.5450	Same
Regulation Name	Chamber, Patient Isolation	Chamber, Patient Isolation	Same
Intended Use	Negative Pressure Isolation Chamber	Negative Pressure Isolation Chamber	Same

Indications for Use	The Carecube is a patient isolation unit (PIU) designed for the temporary isolation of patients within a hospital setting to prevent particulate (biological) cross-contamination between user and patient, while enclosing the contaminated patient from the external environment. Device should only be used in a hospital setting. This is for temporary housing of a patient prior to transfer to an appropriate hospital destination. Transfer to a more permanent hospital setting should occur as soon as possible. The Carecube is designed with features that enable low-moderate complexity medical interventions. This includes the following procedures: blood draw, medication administration, palpating abdomen, cardiac auscultation, and connection to IV line/monitoring cables.	The CAPSULS (Containment and Protection System Utilizing Life Support) is a portable Patient Isolation Unit (PIU), which prevents particulate (biological and radiological) cross-contamination between the patient and the external environment; and with features that enable medical intervention to the patient via end-user supplied medical equipment. The CAPSULS is intended to be used for: • The transport and isolation of patients on aircraft, ambulances, ships and any vehicle capable of safely transporting a patient on a standard litter. • The temporary isolation, with or without transport, of patients within hospitals or medical facilities.	Same except the Carecube indications are a subset of the predicate device because the former is not used for transport.
Provided Sterile	No	No	Same
Reusable	Yes	No	Different Reprocessing validation was performed to ensure safe reuse
Contra-indications	• Morbidly obese patients • Patients weighing less than 45 lbs. or less • Oxygen-rich environments	Unknown	

OTC Use	Yes	Yes	Same
Materials of Construction	• Thermoplastic Polyurethane (TPU) envelope • Powder-coated steel frame	• Clear polyurethane (PUR) or polyvinylchloride (PVC) envelope • Plastic resin stanchions and integral ribs	Different Materials used in both devices represent plastic materials commonly utilized in medical devices and do not raise new issues of safety or effectiveness
Dimensions	118” overall assembled length 54” width 82” height	81” overall length 26” width 20”	Different The Carecube is longer to accommodate stationary use and a medical bed for patient isolation up to 24 hours. Clinical testing demonstrates no new questions of safety or effectiveness.
Weight	120 lbs.	21 lbs.	Different Carecube is heavier based on design for stationary use and does not raise new questions of safety or effectiveness.
Air Filtration	H13 HEPA (99.97% particulates @ 0.3µ)	M95, P100 (99.97% particulates @ 0.3µ) HEPA	Different Both devices have an inline outbound filter, with differences in model type and size. Performance testing demonstrates that, despite the differences, the Carecube is effective in air filtration.

Air Flow	Airflow for patient head to foot is controlled by the fan and HEPA filter blower manufacturer at 150 CFM.	Airflow rate is set by the blower manufacturer at 4 CFM.	Different Air flow capabilities are larger due to the larger room and containment area. Safety and effectiveness is demonstrated in patient comfort and in performance testing.
Pressure	Negative Pressure (NP)	Negative Pressure (NP) Positive Pressure (PP)	Different The CAPSULS™ PIU allows the use of PP or NP which is not necessary for the Carecube's intended use. Both devices utilize NP to isolate a patient and prevent the patient from infecting others. The Carecube negative pressure performance was validated.
Air Changes	35 air changes per hour (ACH)	20-38 air changes per hour (ACH)	Different (The Carecube ACH is within the ACH range for the predicate device.)
Glove Arms	Multiple Glove Arms	Multiple Glove Arms	Same
Other Access Ports	Trunk Ports Conduit Ports Lean-In Windows	Access Ports Conduit Port	Different The Carecube offers additional access ports to facilitate stationary use for patient isolation. The additional ports do not raise different questions of safety or effectiveness and performance was demonstrated.

[1]The Carecube Negative Pressure Isolation Chamber is to be used by a single patient for up to 24 hours of

continuous use. The Carecube Negative Pressure Isolation Chamber canopy is intended for multi-patient re-use with a labeled maximum of ten (10) uses. The glove and trunk ports of the Carecube Negative Pressure Isolation Chamber are intended for single patient use only.

VIII. Performance Data

The following performance data was considered in support of the substantial equivalence determination.

Performance Testing – Bench

The following tests were performed to demonstrate that the proposed Carecube Negative Pressure Isolation Chamber met the applicable design and performance requirements and support a determination of substantial equivalence. Where applicable, testing was done per applicable ISO and other international standards:

- Biocompatibility
- EMC and Electrical Safety
- Usability Testing
- Packaging Testing
- Shelf-Life Testing
- Canopy Robustness
- Functional Performance Testing

Table 5-2. Summary of Performance Testing – Bench and Biocompatibility

Performance	Standard/Test Method	Proposed Device Result	Predicate Result
Biocompatibility			
Cytotoxicity	ISO 10993-5	Non-cytotoxic	Not available
Sensitization	ISO 10993-10	Non-sensitizing	Not available
Intracutaneous Reactivity	ISO 10993-23	Non-irritant	Not available
Acute Systemic Toxicity	ISO 10993-11	Non-toxic	Not available
Volatile Organic Compounds; Particulates	Toxicological Risk Assessment	Non-toxic	Not available
EMC and Electrical Safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6	Pass	Not available
Usability /Human Factors	IEC 62366-1	Pass	Not available
Packaging Testing	ASTM D4169 ASTM D4332	Pass	Pressure/Leak testing
Shelf-life Testing	ASTM F1980	12 months	Not available
Functional Performance Testing			
Canopy Robustness	Internal	Pass	Not available
Airflow and Smoke Testing	Internal	Pass	Not available
Differential Pressure	Internal	Pass	Not available
Tagged particle Clearance	Internal	Pass	Not available
Tagged particle Containment	Internal	Pass	Not available
Noise	Internal	Pass	Not available
Viral Penetration	ASTM F1671	Pass	Not available
Cleaning Resiliency	Internal	Pass	Not available

Cleaning Validation	AAMI TIR30 AAMI ST98	Pass	Not available
Disinfection Validation	AAMI TIR30 AAMI ST98	Pass	Not available
Flammability	16 CFR Part 1610.7	Pass	Not available
Repeat Use Testing	Internal	Pass	Not available
Usage Life Testing			
System Usage Life	Internal	Pass	Not available
Filter usage Life	Internal	Pass	Not available

Biocompatibility
Biocompatibility testing was conducted in accordance with the FDA Guidance Document "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process," September 4, 2020, 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.

Based on the results of the biocompatibility testing performed on the Carecube Negative Pressure Isolation Chamber, the proposed device meets the requirements outlined in ISO 10993-1:2018.

Electrical Safety and Electromagnetic Compatibility (EMC)
EMC and Electrical Safety evaluation was conducted on the proposed Carecube Negative Pressure Isolation Chamber. Based on the results of the EMC testing, the Carecube Negative Pressure Isolation Chamber meets the requirements of IEC 60601-1.

Software Verification and Validation Testing
The proposed Carecube Negative Pressure Isolation Chamber does not contain software; therefore, the proposed device does not require software verification and validation testing.

Performance Testing - Animal
This submission does not include any animal performance testing. It was determined that no such testing was required to demonstrate substantial equivalence.

Performance Testing – Clinical

A non-significant risk (NSR) clinical study was conducted to evaluate patient comfort and environmental safety of the Carecube Negative Pressure Isolation Chamber. This study was intended to evaluate general patient safety and comfort within the Carecube (not associated with a specific disease state or condition), therefore allowing for the use of normal, healthy volunteers to achieve the study endpoints. This study was conducted as a prospective, single center, non-blinded study. The purpose of this study was to ensure patient safety and comfort during containment within the Carecube. Patient safety and comfort was assessed through routine monitoring of subject's vital signs (blood pressure, body temperature, pulse and oxygen saturation), assessment of level of anxiety using the STAID evaluation, as well as monitoring of the Carecube environment (temperature, relative humidity, carbon dioxide (CO2) and atmospheric oxygen (O2) on an hourly basis. Subject data was recorded at baseline, baseline + 5 minutes and hourly, for a minimum of three (3) consecutive hours. This study consisted of a minimum of ten (10) Subjects and came from a cross-section of males and females, ages 21-47 years old.

Table 5-3. Summary of Clinical Testing

Performance	Standard/Test Method	Result	Comparison to Predicate
Human Use Comfort	Internal	Pass	Not available

Based on the results of the study, it was determined that the Carecube Negative Pressure Isolation Chamber is safe for healthcare provider and patient use.

IX. CONCLUSION

The conclusions drawn from the nonclinical and clinical tests 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.