Cyclomedica Australia Pty Ltd
% Ms. Karen Wolfe-Kerker
Official Correspondent
Certus International, Inc.
1422 Elbridge Payne Road, Suite 200
CHESTERFIELD MO 63017

September 1, 2020

Re: K200916
Trade/Device Name: Patient Administration Set (PAS)
Regulation Number: 21 CFR 892.1390
Regulation Name: Radionuclide rebreathing system
Regulatory Class: Class II
Product Code: IYT
Dated: July 10, 2020
Received: July 28, 2020

Dear Ms. Wolfe-Kerker:

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. 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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K200916

Device Name
PATIENT ADMINISTRATION SET

Indications for Use *(Describe)*
The Patient Administration Set is a radionuclide rebreathing system and an accessory intended solely for use with the TechnegasPlus Technegas® Generator. It is designed for use as a conduit system to contain a radionuclide-labeled aerosol and permit respiration by the patient during a functional lung ventilation imaging diagnostic procedure.

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
(As required by 21 C.F.R. §807.92)

Submitted by:	Cyclomedica Australia Pty Ltd Unit 4, 1 The Crescent Kingsgrove NSW 2208 Australia
Company Contact:	Ms. Niamh Mc Aree
Date of Summary:	July 7, 2020
Device Name	Patient Administration Set
Common Name	Radionuclide Rebreathing System
Classification	Class 2
Regulation No.	21 CFR 892.1390
Product Code	IYT
Predicate Device	Patient Administration Set (510(k) # K913416)
Modifications	The modifications include: • Labeling changes to identify the current device owner / manufacturer as well as additional information to comply with current regulatory requirements (e.g. UDI code) • Exhalation Filter changes (new supplier, adopting industry-standard filter composition and design) • Packaging changes (from molded 'shrink-wrap' plastic to industry standard loose plastic bag)
Device Description	The Patient Administration Sets (PAS) consist of a flexible plastic tubing with a distal plastic connector which can be affixed to a radionuclide generator, a T-section connector with (2) one way valves which permits inhalation of the generated radionuclide gas and subsequent absorption of expelled gas during exhalation via a semipermeable microparticle filer. A mouthpiece (choice of soft silicone or hard plastic) is affixed to the proximal end of T-section connector for patient breathing.

Intended Use	The Patient Administration Set is a radionuclide rebreathing system and an accessory intended solely for use with the TechnegasPlus Technegas® Generator. It is designed for use as a conduit system to contain a radionuclide-labeled aerosol and permit respiration by the patient during a functional lung ventilation imaging diagnostic procedure.
Technological characteristics	The PAS has the same technological characteristics as the legally marketed predicate device. New design modifications include changes in the exhalation filter composition to adopt industry standard radionuclide absorption ability.
Design Verification and Validation Testing	Laboratory tests were conducted to establish the performance and reliability characteristics of the modified device. These tests confirmed device dimensions, tolerances, biocompatibility and structural integrity and ensure that the device remains compatible with the TechnegasPlus Technegas™ generator. Test results confirmed that the device is substantially equivalent with the specified predicate device.