March 2, 2021

ClearFlow, Inc,
Serrah Namini
VP RA/QA/CA
140 Technology Drive, Suite 100
Irvine, California 92618

Re: K203394
Trade/Device Name: PleuraFlow System with FlowGlide
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OTK, GBX
Dated: February 3, 2021
Received: February 4, 2021

Dear Serrah Namini:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General 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)*
K203394

Device Name
PleuraFlow® System with FlowGlide®

Indications for Use *(Describe)*
The PleuraFlow® System with FlowGlide® is indicated for use during cardiothoracic surgical procedures and chest trauma. Its Active Clearance Technology® proactively removes clots formed inside the chest tube to prevent or minimize chest tube occlusion with clot. A patent chest tube enables evacuation of blood and fluid from the operative site after closure of the surgical wound and reduces retained blood. The product is indicated for adult and pediatric patients including infant, preadolescent and adolescent patients under clinical settings.

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 (807.92(c))

The following information is provided as required by 21 CFR § 807.92(c) for PleuraFlow® System with FlowGlide™ 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Date of Submission: Nov 17, 2020

Applicant:
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Primary Contact Person:
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Device Proprietary Name: PleuraFlow® System with FlowGlide®

Device Common Name: Wound drain catheter system

Regulatory Class and Name: Class II, 878.4780 Powered suction pump

Product Codes: OTK and GBX

Predicate Device: Predicate device is the PleuraFlow Catheter System (K163139 and number K182067) as well as K191733 by ClearFlow, Inc.

Device Description: The PleuraFlow® System with FlowGlide(R) PFFG3 is a modification to our current PleuraFlow® System with FlowGlide(R) (predicate). The primary components of the System are the Chest Tube and the Clearance Apparatus. The Chest Tube is connected to a Clearance Apparatus, which is connected to the tubing from the drainage canister.

The Clearance Apparatus that is part of the PleuraFlow System with FlowGlide consists of a Guide Tube with a magnetic shuttle and a PTFE-coated Clearance Wire with a Loop set on its distal end. The Clearance Apparatus is advanced into the PleuraFlow Chest Tube using a magnetic Shuttle. When indicated, the Clearance Wire and Loop is advanced and retracted within the PleuraFlow with FlowGlide Chest Tube to proactively prevent or break up and clear any tube obstructions or clogging to keep the tube patent. The PleuraFlow System with FlowGlide, PFFG3, has a new shuttle design that includes a spring activated button to allow the user to increase the magnetic force when needed. The range of magnetic force is the same as predicate.

Indication For Use: The PleuraFlow® System with FlowGlide™ is indicated for use during cardiothoracic surgical procedures and chest trauma. Its Active Clearance Technology proactively removes clots formed inside the chest tube to prevent or minimize chest tube occlusion with clot. A patent chest tube enables evacuation of blood and fluid from the operative site after closure of the surgical wound and reduces retained blood. The product is indicated for adult and pediatric patients including infant, preadolescent and adolescent patients under clinical settings.

Technological Characteristics and Performance Data:

The performance of the new models of the PleuraFlow System with FlowGlide® was shown to be substantially equivalent to the cleared models (predicate) through bench testing.

Performance of new configuration of the PleuraFlow System was verified using the following testing as summarized in the submission:

- Test for actuation and tracking of the Clearance Wire and Loop through the coated chest tube tortuous path
- Functional Testing of the Shuttle
- Coupling force testing of the Shuttle to Clearance Wire and Loop
- Force to actuate, force to move the Shuttle along the guide tube of the clearance apparatus while coupled to the Clearance Wire and Loop
- Magnetic Flux testing, magnetic field in proximity to the device
- Button cycle testing, test for button function after repeated uses
- Force to separate the shuttle enclosure
- Transportation simulation.
- Tensile strength of the drain tubing to drain barb

The biocompatibility of materials remains the same and as such, the new device meets ISO 10993-1 applicable requirements. The new device is provided sterile and single use and meets ISO 11135:2014 requirements.

The safety and effectiveness of the predicate have been previously demonstrated through design validation and verification that were cleared under 510(k) premarket notification (K163139 and number K182067). No clinical performance was deemed necessary according to Risk Management

assessment and evaluation. Use of the predicate devices for more than 10 years has demonstrated safety and effectiveness for patients recovering after surgery and who were placed with the PleuraFlow System with Active Clearance Technology® (ACT®). The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device

Results from performance testing of the new models of PleuraFlow System with FlowGlide® PFFG3, demonstrates that these are suitable for the intended use and did not raise new issues of safety and effectiveness when compared to the predicate models.

Conclusion:

The Indication for Use for the new configurations is same as the predicate. The fundamental design and technological characteristics are the same as the predicate. Risk assessment, verification and validation of the PleuraFlow System with FlowGlide®, PFFG3, do not raise any additional concerns regarding safety and effectiveness and they are substantially equivalent to the predicate system.