DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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November 30, 2016

ClearFlow, Inc.
Dr. Dov Gal, DVM, MBA
Vice President, Regulatory Affairs, Quality Assurance and Clinical
1630 S. Sunkist St., Suite E
Anaheim, California 92806

Re: K163139
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: November 7, 2016
Received: November 9, 2016

Dear Dr. Gal:

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,

Jennifer R. Stevenson -A

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

Indications for Use Statement

510(k) Number: K163139

Device Name: PleuraFlow® System with FlowGlide™

Indications 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.

Prescription Use ___**X**____ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

The following information is provided as required by 21 CFR § 807.87 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: November 7, 2016

Applicant:
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Device Proprietary Name: PleuraFlow® System with FlowGlide™

Device Common Name: Introduction/drainage; wound drain catheter system.

Regulatory Class and Name: Class II, Powered Suction Pump

Product Codes: OTK and GBX

Predicate Device: Predicate device is the PleuraFlow Catheter System (K150042) by ClearFlow, Inc.

Reference Device: ADAPt Universal Laparoscopic Port K082156.

Device Description: The PleuraFlow® System with FlowGlide™ is an extension of the PleuraFlow® System (predicate). The primary components of the System are the Chest Tube and the Clearance Apparatus. The PleuraFlow System with FlowGlide includes four (4) models: PFFG-20, PFFG-24, PFFG-28 and PFFG-32. Each of the four (4) models includes a Chest Tube with a Cut Length of 19 inches (48.3 cm) with graduated measurements in centimeters from the distal eyelet. Each of these chest tubes has six (6) eyelets distributed along an Effective Drainage Length of 4 inches (10.2 cm). The Effective Drainage Length is defined as the length of the Chest Tube having eyelets for the influx of fluid. Each Chest Tube has a barium stripe to facilitate visualization in the chest cavity under X-ray. All models include a Chest Tube with FlowGlide applied to the internal and external surfaces to reduce friction and allow easier sliding of the Clearance Wire assembly. 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 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 open.

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.

Performance Data:

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

Performance of the PleuraFlow System with FlowGlide™ coating was verified using the following testing summarized in the submission:

- Tensile strength / Force at break
- Freedom from leakage
- Flow rate
- Kink testing
- Force to actuate Clearance Wire and Loop through coated chest tube
- Test for actuation of the Clearance Wire and Loop through the coated chest tube tortuous path
- Fatigue testing
- Integrity / durability of the FlowGlide coating
- Simulated use
- Transportation simulation.

A biological risk assessment for the addition of FlowGlide™ coating to the Chest Tube was performed in accordance with ISO 10993-1, a summary of test results are provided in the submission.

The safety and effectiveness of the predicate have been previously demonstrated through design validation and verification that were cleared under 510(k) premarket notification K150042. Use of the predicate device over the last six (6) years has shown that the product has significantly reduced the complications for patients recovering from heart surgery and who were treated with the PleuraFlow System with Active Clearance Technology® (ACT®) versus other conventional chest tubes.

Results from performance testing of the PleuraFlow System with FlowGlide™ demonstrate that the modified device is suitable for its intended use and did not raise new issues of safety and effectiveness when compared to the predicate device.

The effectiveness of the modified device is enhanced by the FlowGlide™ coating, which provides a low friction surface on the inside and outside of the chest tube.

Conclusion: The device Indication for Use is same as the predicate. The design and technological characteristics are same as the predicate. Risk benefit analysis, verification and validation and biocompatibility testing of the PleuraFlow System with FlowGlide™ do not raise any additional concerns regarding safety and effectiveness and may be considered substantially equivalent to the predicate device.