DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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January 20, 2016

Clearflow Incorporated
Mr. Dov Gal
Vice President Regulatory Affairs and Quality Assurance
1630 South Sunkist St, Suite E
Anaheim, California 92806

Re: K153681
Trade/Device Name: PleuraFlow® System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OTK, GBX
Dated: September 17, 2015
Received: September 18, 2015

Dear Mr. 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 yours,

Jennifer R. Stevenson -S

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

Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for **PleuraFlow® System** with Short Effective Drainage Length (SEDL) Chest Tube 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: December 21, 2015

Applicant:
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Device Proprietary Name: PleuraFlow® System

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

Regulatory Class and Name: Class II, Powered Suction Pump

Product Codes: OTK and GBX

Indication For Use: The PleuraFlow System 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.

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

Device Description: The PleuraFlow System is comprised of a silicone Chest Tube and a Clearance Apparatus. Currently the PleuraFlow Chest Tube is available in four (4) models with standard sizes (20FR, 24FR, 28FR and 32FR). The Chest Tubes of currently marketed and above-references PleuraFlow System models include 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. The current Chest Tube models are available with a Cut Length of 19 inches (48.3 cm) with graduated measurements in centimeters from the distal eyelet. Each Chest Tube has a barium stripe to facilitate visualization. The Chest Tube is connected to a Clearance Apparatus, which is connected to the tubing from the drainage canister.

The new PleuraFlow System model is similar to the current models except for the Chest Tube, which has four eyelets instead of 6 eyelets. The short Effective Drainage length is only available with a 20FR Chest Tube identifies as: Short Effective Drainage Length (SEDL). This

model has four (4) eyelets distributed along an Effective Drainage Length of 2 inches (5.1 cm). This Chest Tube model has a Cut Length of 19 inches (48.3 cm) with graduated measurements in centimeters from the distal eyelet and a barium stripe to facilitate visualization, as all of the currently marketed Chest Tubes have. Same as the marketed models, the 20FR SEDL 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 20FR SEDL Chest Tube is same as the predicate. It consists of a Guide Tube and a PTFE-coated Clearance Wire with a Loop set on its distal end, bent at a 105-degree angle. 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 Chest Tube to proactively prevent or break up and clear any tube obstructions or clogging to keep the tube open.

The PleuraFlow System with 20FR Short Effective Drainage Length (SEDL) Chest Tube can be used when the surgeon determines that a chest tube with a shorter length of drainage holes, 2“ (5.1 cm) is needed. This includes patients having smaller dimension chests (length of torso) that cannot accommodate Chest Tubes with longer EDLs.

Performance Data:

The safety and effectiveness of the PleuraFlow System has been previously demonstrated through design validation and verification that were cleared under 510(k) premarket notification K093565 and K150042. The biocompatibility evaluation for the PleuraFlow System was conducted under predicate 510(k) K093565, in accordance with the FDA Blue Book Memorandum #G95-1 and International Standard ISO 10993-1.

Mechanical testing was performed to establish substantial equivalence to the predicate 510(k) K093565. Testing was performed in accordance with BS EN 1617:1997 and BS EN 1618:1997. These included flow rate and tensile strength testing.

Device performance has been further demonstrated through post-

market data published in the Journal of Thoracic and Cardiovascular Surgery [Sirch J, Ledwon M, Püski T, Grossmann I, Boyle EM, Pfeiffer S, Fischlein T. Active Clearance of Chest Drainage Catheters Reduces Retained Blood. J Thorac Cardiovasc Surg. 2015 Oct 22. pii: S0022-5223(15)01970-4. doi: 10.1016/j.jtcvs.2015.10.015].

Conclusion: The device Indication for Use is same as the predicate. The evaluation of the PleuraFlow System does not raise any additional concerns regarding safety and effectiveness and may be considered substantially equivalent to the predicate device.