



Food and Drug Administration
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June 2, 2015

ClearFlow Incorporated
Dr. Dov Gal, DVM
Vice President Regulatory Affairs, Quality Assurance and Clinical Affairs
1630 South Sunkist Street, Suite E
Anaheim, California 92806

Re: K150042
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: April 14, 2015
Received: April 20, 2015

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" (21CFR 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

Indications for Use

510(k) Number (if known)
150042

Device Name
PleuraFlow® System

Indications for Use (Describe)

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for **PleuraFlow® System** 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: April 14, 2015

Applicant: Clear Flow, Inc.
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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 Catheter System (K093565) by ClearFlow, Inc., AKA Clear Systems, Inc.

Device Description: The PleuraFlow System is comprised of a silicone Chest Tube and a Clearance Apparatus. The PleuraFlow Chest Tube is available in four (4) standard sizes (20FR, 24FR, 28FR and 32FR). Each Chest Tube has 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 Clearance Apparatus 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 patent.

Indications 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.

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) (K093565). Performance has been further demonstrated through post-market data.

Use of the device over the last four (4) years has shown that the product has significantly reduced the complications for patients who have received treatment with PleuraFlow versus other products during and after surgery.

Studies have linked both chest tube clogging and retained pericardial blood with POAF.^{2, 10} There is a substantial body of literature illustrating that shunting blood through pericardial windows to divert the blood to the pleural spaces can reduce POAF.¹⁰ demonstrates by adhering to a protocol developed to maximize chest tube patency, POAF can be reduced. Consistent with prior studies, this link appears to be related to reducing RBS. A manuscript titled “Reduction in Interventions for Post Operative Effusions and Atrial Fibrillation with Active Clearance of Chest Drainage Catheters” was submitted to the Journal of Thoracic and Cardiovascular Surgery. Authors are Sirch J.1, Ledwon M.1, Püski T.1, Grossmann I.1, Boyle EM.2, Pfeiffer S.1, Fischlein T.1 From the following institutions:

1. Cardiac Surgery, Heart Center, Paracelsus Medical University, Nuremberg, Germany,
2. St. Charles Medical Center, Bend, Oregon, United States.

Conclusion:

The evaluation of the PleuraFlow System does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to the predicate device.