July 26, 2019

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

Re: K191733
Trade/Device Name: The ZIP
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OTK, GBX
Dated: June 26, 2019
Received: June 28, 2019

Dear Dov 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. 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K191733

Device Name
THE ZIP

Indications for Use *(Describe)*
THE ZIP is an accessory to the PleuraFlow® System with FlowGlide®. It 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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for THE ZIP 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:** June 26, 2019

**Applicant:**
ClearFlow, Inc.
1630 S. Sunkist St., Suite E
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**Device Proprietary Name:** THE ZIP

**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 System with FlowGlide (K163139) by ClearFlow, Inc.

**Device Description:** THE ZIP accessory is a non-sterile reusable external, hand-held free-standing magnetic shuttle that is used to couple and move the Clearance Wire of the PleuraFlow System. It can be used instead of the PleuraFlow System's integral Shuttle when the user determines that increase of magnetic coupling is needed to break up and clear any tube obstructions or clogging to keep the tube patent.

**Indication For Use:** THE ZIP is an accessory to 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 ZIP was shown to be substantially equivalent to the PleuraFlow System with FlowGlide® (predicate) through bench testing.

Performance of THE ZIP was verified using the following testing summarized in the submission:

- Decoupling Force
- Magnetic Flux

- Functionality
- Drop.

Results from performance testing of THE ZIP demonstrate its suitability for the intended use and do not raise new issues of safety and effectiveness when compared to its predicate.

**Conclusion**: THE ZIP Indications For Use are the same and technological characteristics are similar to the predicate. Risk benefit analysis, verification and validation and biocompatibility of the subject device do not raise any additional concerns regarding safety and effectiveness. Accordingly, THE ZIP is substantially equivalent to its predicate.