DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 21, 2014

Teleflex Medical, Inc.
% Ms. Holly Hallock
Regulatory Affairs Specialist
2917 Weck Dr.
Po Box 12600
Research Triangle Park, North Carolina 27709

Re: K140197
Trade/Device Name: Pleur-evac Plus Continuous Reinfusion And Autotransfusion System
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II
Product Code: CAC
Dated: September 9, 2014
Received: September 10, 2014

Dear Ms. Hallock,

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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K140197

Device Name: Pleur-evac® Plus Continuous Reinfusion Autotransfusion System

Indications for Use:

- For the collection of autologous blood from the patient's pleural cavity or mediastinal area for reinfusion purposes in trauma and post-operative situations,
- To evacuate air and/or fluid from the chest cavity or mediastinum,
- To help prevent air and/or fluid from re-accumulating in the chest cavity or mediastinum,
- To help re-establish and maintain normal intra-thoracic pressure gradients,
- To facilitate complete lung re-expansion to restore normal breathing dynamics.

Prescription Use XX (Part 21 CFR 801 Subpart D) AND/OR **Over-the-counter use __** (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

Pleur-evac® Plus Continuous Reinfusion Autotransfusion System

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-4918
Fax: 919-433-4996

B. Contact Person

Holly Kornegay
Regulatory Affairs Specialist

C. Date Prepared

January 24, 2014

D. Device Name

Trade Name:	Pleur-evac® Plus Continuous Reinfusion Autotransfusion System
Common Name:	Autotransfusion Apparatus
Regulatory Classification:	Class II
Regulation Number:	21 CFR 868.5830
Product Code:	CAC

E. Device Description

Provided as a sterile unit and intended for single patient use, the A-9250LF Pleur-evac® Plus Continuous Reinfusion Autotransfusion System is a three-chamber, collection/reinfusion system used for the collection and continuous reinfusion of autologous blood. By attaching a blood transfer bag, which is available as an accessory item, the A-9250LF Pleur-evac® Plus serves as a bag reinfusion system with a non-pyrogenic fluid path. When autotransfusion is complete, the A-9250LF Pleur-evac® Plus can serve as a water seal/dry suction chest drainage collection unit.

F. Indications for Use

Pleur-evac® Plus Continuous Reinfusion Autotransfusion Systems are indicated for:

- For the collection of autologous blood from the patient's pleural cavity or mediastinal area for reinfusion purposes in trauma and post-operative situations,

- To evacuate air and/or fluid from the chest cavity or mediastinum,
- To help prevent air and/or fluid from re-accumulating in the chest cavity or mediastinum,
- To help re-establish and maintain normal intra-thoracic pressure gradients,
- To facilitate complete lung re-expansion to restore normal breathing dynamics.

G. Contraindications

Pleur-evac® Plus Continuous Reinfusion Autotransfusion Systems are contraindicated for:

- Pericardial, mediastinal, or systemic infections,
- Pulmonary and respiratory infection or infestation,
- Presence of malignant neoplasms,
- Coagulopathies,
- Suspected thoraco-abdominal injuries with possible enteric contamination,
- Impaired renal function,
- Intraoperative thoracic or mediastinal cavity use of topical thrombin, microfibrillar hemostatic agents or providine-iodine antiseptic gels or solutions and non I.V. compatible antibiotics.

H. Substantial Equivalence

The proposed Pleur-evac® Plus Continuous Reinfusion Autotransfusion System is substantially equivalent to the predicate device:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Deknatel® A-9150 Pleur-evac® Plus Continuous Reinfusion & Autoinfusion System	Pfizer Hospital Products Group, Inc.	K911656	August 13, 1991

I. Comparison to Predicate Devices

The Pleur-evac® Plus Continuous Reinfusion Autotransfusion System has the same indication for use and functional characteristics as the predicate system. The proposed modifications are changes in the material and manufacturing process of the collection tubing and in the material of the high negative pressure relief valve (HNRV) filter. Additionally, there are proposed changes to the material of the faceplate, the back and the universal connector.

J. Materials

All patient contacting materials are in compliance with ISO 10993-1:2009 and FDA Bluebook Memorandum G95-1.

K. Technological Characteristics

A comparison of the technological characteristics of the proposed Pleur-evac® Plus Continuous Reinfusion Autotransfusion System and the predicate has been performed. The results of this comparison demonstrate that the Pleur-evac® Plus Continuous Reinfusion Autotransfusion System collection tubing, HNRV filter, faceplate, back and universal connector are equivalent to the marketed predicate device in technological characteristics. A summary of these comparisons is included in the table below. For a complete comparison chart, please refer to Section 16.

Technological Characteristics	Predicate Device, A-9150	Proposed Device, A-9250LF	Comparison
Indications for Use	• For the collection of autologous blood from the patient's pleural cavity or mediastinal area for reinfusion purposes in trauma and post-operative situations, • To evacuate air and/or fluid from the chest cavity or mediastinum, • To help prevent air and/or fluid from re-accumulating in the chest cavity or mediastinum, • To help re-establish and maintain normal intra-thoracic pressure gradients, • To facilitate complete lung re-expansion to restore normal breathing dynamics.	• For the collection of autologous blood from the patient's pleural cavity or mediastinal area for reinfusion purposes in trauma and post-operative situations, • To evacuate air and/or fluid from the chest cavity or mediastinum, • To help prevent air and/or fluid from re-accumulating in the chest cavity or mediastinum, • To help re-establish and maintain normal intra-thoracic pressure gradients, • To facilitate complete lung re-expansion to restore normal breathing dynamics.	Same
Collection	Yes, the A-9150 featured a collection compartment for either gravity or suction drainage and collection.	Yes, the A-9250LF features a collection compartment for either gravity or suction drainage and collection.	Same
Reinfusion	Yes, when connected to an accessory bag, the A-9150 was capable of reinfusion and autotransfusion via a reinfusion port in the collection chamber base.	Yes, when connected to an accessory bag, the A-9250LF is capable of reinfusion and autotransfusion via a reinfusion port in the collection chamber base.	Same

L. Performance Data

Teleflex has performed bench testing to verify that the performance of the proposed Pleur-evac® Plus Continuous Reinfusion Autotransfusion System is substantially equivalent to that of the predicate device and that the Pleur-evac® Plus Continuous Reinfusion Autotransfusion System is seamlessly interchangeable with the predicate device. Various functionality tests were performed to ensure that the collection tubing, HNRV filter, faceplate, back and universal connector will perform as intended. The test results are summarized below. For more details, please refer to Section 23.

Product Description	Quantity	Test Parameters	Results
Kink	300	A visual inspection must be performed to ensure that all pouched tubing is coiled correctly without kinks.	Pass
Tubing Clamp Leak	60	No leaks in the tubing when clamped at 60 cm H2O for vacuum and at 4 cm H2O positive pressure minimum.	Pass
Tubing Collapse	300	No tubing collapse at 340 cm H2O negative pressure.	Pass
ATS Connector Pull Test	60	Separation force of ATS Connector from tubing.	Pass
Inter- Chamber Leak Test	60	All compartments must hold the indicated volumes with liquid spillover occurring only at the spillover level.	Pass
Leak Integrity Test	60	The unit shall be airtight when operated at negative pressure 60 cm H_20	Pass
Burst Test	60	The unit shall have a minimum burst strength of 5 psig (PSI Gauge) at welded joints with all openings to atmosphere sealed	Pass
Reinfusion Tube Separation Force Test	60	The separation force of the tube and spring from the reinfusion port and the tube from the spike port shall be a minimum of 10 lbs axially.	Pass

M. Conclusion

Based upon the comparative test results, the proposed Pleur-evac® Plus Continuous Reinfusion Autotransfusion System is substantially equivalent to the predicate device cleared to market via 510(k) K911656. The modifications made to the proposed

Pleur-evac® Plus Continuous Reinfusion Autotransfusion System do not introduce any new issues of safety and effectiveness.