November 29, 2018

Centese, Inc.
Evan Luxon
President & CEO
3929 Harney St Suite 3008
Omaha, Nebraska 68131

Re: K181667
Trade/Device Name: Thoraguard System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: BTA
Dated: November 9, 2018
Received: November 13, 2018

Dear Evan Luxon:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2018.11.29 15:54:34 -05'00'

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

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)*
K181667

Device Name
Thoraguard System

Indications for Use *(Describe)*
The Thoraguard System is intended to be used for aspiration and removal of surgical fluids, tissue, gases, bodily fluids or infectious materials. The Thoraguard System is indicated for all situations where chest drains are applied – especially for thoracic drainage in the pleural and mediastinal cavity in situations such as pneumothorax, after cardiac or thoracic surgery (post-operative), thorax injury, pleural effusion, pleural empyema or other related conditions. The Thoraguard System is intended for use on patients in appropriate care 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."

This summary of 510(k) safety and effectiveness information for the Centese Thoraguard System is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter

Centese, Inc.
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Omaha, NE 68131

Phone: (402) 417-0740
Email: eluxon@centese.com

Contact Person: Evan Luxon, President & CEO
Date Prepared: June 22, 2018

2. Device

Name of Device: Thoraguard System
Common or Usual Name: Powered Suction Pump
Classification Name: Pump, Portable, Aspiration (Manual or Powered) [21 CFR 878.4780]
Regulatory Class: II
Product Code: BTA

3. Predicate Device

Thopaz+ Suction Pump by Medela AG (K141553)

4. Device Description

The Thoraguard Surgical Drainage System is an AC/DC powered suction pump designed for the aspiration and removal of surgical fluids, tissue, gases, bodily fluids or infectious materials. The Thoraguard System offers automated drainage functionality, acquisition and display of drainage information, and safety alarms associated with changes in patient output.

The Thoraguard System consists of the three sub-systems: the Thoraguard Control Module, a reusable electronic device for generating and regulating suction; the Thoraguard Drainage Kit, a disposable drainage canister and dual lumen drainage tubing set; and the Thoraguard Chest Tube Kit, a dual lumen drainage catheter with a passive valve and filter.

Similar to traditional chest drainage systems, the Thoraguard System drains accumulated blood and fluid through the chest tube using regulated suction. The control module facilitates this drainage automatically and works in conjunction with the drainage kit to function as a powered suction pump. The system may be used with any drainage catheter; when used with the Thoraguard Chest Tube Kit, the system provides automated clearance of clogs within the chest tube itself. During normal operation, the control module displays relevant system information via the touchscreen graphical user interface.

5. Indications for Use

The Thoraguard System is intended to be used for aspiration and removal of surgical fluids, tissue, gases, bodily fluids or infectious materials. The Thoraguard System is indicated for all situations where chest drains are applied – especially for thoracic drainage in the pleural and mediastinal cavity in situations such as pneumothorax, after cardiac or thoracic surgery (post-operative), thorax injury, pleural effusion, pleural empyema or other related conditions. The Thoraguard System is intended for use on patients in appropriate care settings.

6. Comparison of Technological Characteristics with Predicate Device

The Thoraguard system has substantially equivalent technological characteristics as the predicate device. Similarities to the predicate device include the following:

- Pump Type
- Suction capacity
- Max Vacuum
- Vacuum regulator type
- Vacuum gauge type

Differences in the technologic characteristics between the Thoraguard System and the predicate device do not raise different questions of safety and effectiveness. Centese has confirmed equivalent performance of the Thoraguard System to the predicate device using accepted scientific methods for assessing the effect of these different characteristics, such as bench testing.

7. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Performance Bench Testing

The Thoraguard System has been verified for its intended use by conducting a series of bench tests that qualified its functionality, integrity and performance. The testing performed included suction performance tests per ISO 10079-1:2015, catheter performance test per EN 1617:1997, and system-level verification testing.

Biocompatibility Testing

Biocompatibility for the Thoraguard chest tube has been assessed in accordance with ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system.

Electrical Safety and Electromagnetic Compatibility (EMC)

The Thoraguard Surgical Drainage System has been evaluated for electrical safety and electromagnetic compatibility (emissions and immunity) and has passed all electrical safety and EMC testing requirements.

Software Verification and Validation Testing

Software verification and validation has been performed and the Thoraguard System has passed all testing requirements.

Usability Testing

Centese has performed usability validation of the Thoraguard System and has found the it to be safe and effective for the intended users, uses, and use environments.

8. Conclusions

Results from bench testing for design verification and validation have demonstrated acceptable performance on all tests to indicate that the Thoraguard System is suitable for its intended use and is as safe and effective as the predicate device to support a determination of substantial equivalence.