April 9, 2018

Rebound Therapeutics
Ms. Jane Metcalf
Vice President of Regulatory Affairs
13900 Alton Parkway, Suite 120
Irvine, California 92618

Re: K180372
Trade/Device Name: Aurora Evacuator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 7, 2018
Received: February 12, 2018

Dear Ms. Metcalf:

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.

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.

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,

Jennifer R. Stevenson -S3

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)*
K180372

Device Name
AURORA Evacuator

Indications for Use *(Describe)*
The AURORA Evacuator is a powered instrument with a handpiece intended for removal of soft tissue and fluids under direct visualization. Types of direct visualization may include laparoscopic, pelviscopic, endoscopic, percutaneous, and open. Applications include those when access to the surgical site is limited, such as Neurosurgical/Spinal and ENT/ Otolaryngological.

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.

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1) SUBMITTER

Rebound Therapeutics Corporation
13900 Alton Parkway, STE 120
Irvine, CA 92618

Contact Person: Jeffrey J. Valko, President and CEO
Telephone: (949) 633-2747
Email: jvalko@reboundtx.com

Contact Person: Jane Metcalf, Vice President of Regulatory Affairs
Telephone: (949) 525-1493
Email: jmetcalf@reboundtx.com

Date Prepared: April 3, 2018

2) DEVICE

Name of Device: AURORA Evacuator
Common or Usual Name: Aspirator
Classification Name: Electrosurgical, Cutting & Coagulation & Accessories
Regulatory Class: II
Product Code: GEI

3) PREDICATE DEVICE

Primary Predicate: NICO Myriad, 11GA, K161307
Secondary Predicate: ConMed Corporation, Frazier 8Fr, Class II, 510(k) Exempt

4) DEVICE DESCRIPTION

The AURORA Evacuator is provided sterile, for single-use only. It is a disposable, handheld, aspiration device designed to remove fluids and soft tissue during minimally invasive surgical procedures. The AURORA Evacuator consists of a stainless-steel suction wand connected to a plastic handle.

The stainless-steel suction wand is configured with an aspiration window, near its distal end, for fluid and soft tissue to enter. Internal to the suction wand is a shaft with a whisk-shaped configuration at its distal end. The whisk-shaped configuration is aligned with the aspiration window. The proximal end of the shaft is connected to a battery powered motor in the handle.

The interior of the plastic handle contains the battery powered motor, batteries, electrical circuitry and the suction tubing. The suction tubing connects the stainless-steel suction wand to operating room vacuum. On the exterior of the handle is a tear-dropped shaped vent for user control of vacuum strength, a green light that illuminates when power is available, and a button for user activation of the motor.

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The AURORA Evacuator is shipped in a non-functional state that requires removal of a pull tab from the handle to initiate power to the device.

There are three (3) configurations of the AURORA Evacuator; AURORA Evacuator -13, AURORA Evacuator -10 and AURORA Evacuator -7. All configurations are fabricated from the same materials and electrical components. The only difference among the configurations is the working length of the wand component. The wand working lengths are 13cm, 10cm, and 7cm, respectively.

5) STATEMENT OF INTENDED USE

The AURORA Evacuator is a powered instrument with a handpiece intended for removal of soft tissue and fluids under direct visualization. Types of direct visualization may include laparoscopic, pelviscopic, endoscopic, percutaneous, and open. Applications include those when access to the surgical site is limited, such as Neurosurgical/Spinal and ENT/Otolaryngological.

6) SUMMARY OF TESTING

The following testing was conducted to demonstrate the safe and effective use of the AURORA Evacuator and its' substantial equivalence to the primary predicate.

- Biocompatibility Testing per ISO 10993-1 - Cytotoxicity (MEM Elution), Sensitization (Kligman Maximization), Irritation (Intracutaneous Injection), Systemic Toxicity (Systemic Injection, Material Mediated Pyrogenicity)
- Electrical Safety and Enclosure Protection per IEC 60601-1 and IEC 60529-1
- Emissions and Immunity per IEC 60601-1-2
- Particulate Testing per USP 36 <788>:
- Sterilization per ISO 11135-1 to validate a SAL of 10^{-6}
- Packaging and Shelf-life per ISTA 2A and ASTM F1980
- Verification of product specifications including, materials, multiple bonds evaluations, physical characteristics, audible characteristics, rotational speeds, duration of use and operational temperatures
- Validation of product performance using surrogate soft tissue materials and surrogate fluid materials

7) SUMMARY TECHNOLOGICAL CHARACTERISTICS

The AURORA Evacuator has two (2) modes of operation; one (1) for aspiration and another for cutting. For aspiration, the AURORA Evacuator connects to an external vacuum source that is present in the operating room. For cutting, the AURORA Evacuator utilizes a rotating whisk that is internal to the wand.

To aspirate, the surgeon covers the suction vent on the device's handle and positions the aspiration window so that vacuum draws fluid and soft tissue through the window and into the wand. The aspirant travels through the wand, into the suction tubing and is deposited into the waste receptacle connected to the operating room vacuum-line.

To cut soft tissue, the surgeon pushes the motor activation button on the exterior of the handle causing the whisk to rotate. Vacuum is used to draw soft tissue through the aspiration window and into the rotating whisk. The soft tissue is cut by the rotating whisk and transported to a collection

receptacle connected to the operating room vacuum-line. Soft tissue cutting can only occur inside of the wand.

8) COMPARISON TO PREDICATE

Comparing the AURORA Evacuator to the primary predicate shows that there are three main technological differences; vacuum source, energy source, and tissue cutting. The primary predicate uses an internally controlled vacuum source instead of an external vacuum source. Its energy source is from a wall outlet rather than direct current from internal batteries. Finally, the primary predicate cuts both soft tissue and solid tissue using a scissoring action. The AURORA Evacuator only cuts soft tissue and uses a rotating whisk rather than scissoring. All three of these differences have been analyzed and tested. Results show no new or different questions of safety and effectiveness.

9) CONCLUSION

Upon reviewing the performance data provided in this submission and comparing indicated use, design, materials, principle of operation and overall technological characteristics, the AURORA Evacuator has been determined, by Rebound Therapeutics Corporation, to be substantially equivalent to the primary predicate.