February 12, 2019

Rebound Therapeutics Corporation
Mr. Donald Atienza
Director of Quality Assurance and Regulatory Affairs
13900 Alton Parkway, Suite 120
Irvine, California 92618

Re: K190075
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: January 9, 2019
Received: January 16, 2019

Dear Mr. Atienza:

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: 2019.02.12 14:42:41 -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)*
K190075

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
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Date Prepared: February 11, 2019

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 Predicates: AURORA Evacuator-7, AURORA Evacuator-10, AURORA Evacuator-13, cleared under 510(k) #K180372
Secondary Predicate(s): None

4) PURPOSE OF SUBMISSION

The purpose of this submission is to achieve market clearance for two (2) modifications to the AURORA Evacuator. The primary modification is a product line extension to include two (2) larger diameter suction wands with an elongated whisk. This change adds six (6) new configurations to the original 3 configurations. See Table 5-1 below. The other modification is to change the identification label on the device handle to include French size.

Note that model numbers have also changed. The original three (3) model numbers submitted in K180372 were “Aurora Evacuator-13”, “Aurora Evacuator-10” and “Aurora Evacuator-7”. These model numbers have been changed to “AURORA Evacuator-9Fx13cm”, “AURORA Evacuator-9Fx10cm”, and “AURORA Evacuator-9Fx7cm”, respectively

5) DEVICE DESCRIPTION

There is a total of nine (9) devices in the AURORA Evacuator product line; three (3) from the original 510(k), K180372, and six (6) in this 510(k). All members of the product line have the same design and mode of operation. See Table 5-1 below.

TABLE 5-1 Summary of Device Configurations

	Model #	Wand Working Length (cm)	Wand OD (mm)	Wand ID (mm)
Predicates	AURORA Evacuator-9Fx7cm	7	3.0	2.6
	AURORA Evacuator-9Fx10cm	10	3.0	2.6
	AURORA Evacuator-9Fx13cm	13	3.0	2.6
Subject of this Submission	AURORA Evacuator-10Fx7cm	7	3.4	3.0
	AURORA Evacuator-10Fx10cm	10	3.4	3.0
	AURORA Evacuator-10Fx13cm	13	3.4	3.0
	AURORA Evacuator-11Fx7cm	7	3.6	3.2
	AURORA Evacuator-11Fx10cm	10	3.6	3.2
	AURORA Evacuator-11Fx13cm	13	3.6	3.2

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 with an exiting vacuum tube. A barb connector at the end of the exiting vacuum tube is intended to connect to operating room suction.

The 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 rotatable shaft with wire loops. The wire loops are aligned with the aspiration window and are intended to physically break-up soft tissue. The rotatable shaft is connected to a battery powered motor.

The motor and batteries are housed in the ergonomically designed handle. A green power indicator light is located on the top portion of the handle to show that power is available to the device. The handle also contains a suction control vent for user vacuum control and a motor control button for user activation of the rotating wire loops.

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.

6) 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.

7) SUMMARY OF TESTING

The following testing was conducted or adopted to demonstrate the safe and effective use of the modified AURORA Evacuators and substantial equivalence to the predicate.

- Biocompatibility Testing per ISO 10993-1, including Cytotoxicity (MEM Elution), Sensitization (Kligman Maximization), Irritation (Intracutaneous Injection), Systemic Toxicity (Systemic Injection), Material Mediated Pyrogenicity was adopted from the predicate since materials of construction are identical.

- Electrical Safety and Enclosure Protection per IEC 60601-1 and IEC 60529-1 was adopted from the predicate since the electrical configuration and design has not changed.
- Emissions and Immunity per IEC 60601-1-2 was adopted from the predicate since the electrical configuration has not changed
- Particulate Testing per USP 36 <788> was adopted from the predicate since there is no change to configuration accept for wand diameter.
- Sterilization per ISO 11135-1 to validate a SAL of 10^{-6} was adopted using the predicate data.
- Packaging and Shelf-life per ISTA 2A and ASTM F1980 were adopted from the predicate since there are no changes to packaging configuration or package design.
- 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 material.

8) SUMMARY TECHNOLOGICAL CHARACTERISTICS

The AURORA Evacuator has two (2) modes of operation: one (1) for aspiration and one (1) for breaking up tissue. For aspiration, the AURORA Evacuator uses an external vacuum source present in the operating room. To aspirate, the surgeon covers the suction control vent and positions the aspiration window so that vacuum draws fluid and smaller pieces of soft tissue through the window, into the wand, through the exiting vacuum tube and into a collection receptacle.

For breaking-up soft tissue the AURORA Evacuator uses rotating wire loops that are located inside the wand. Batteries in the handle of the device power a micro gear motor that causes the wire loops to rotate when the motor control button is pushed. The surgeon positions the aspiration window against the tissue to be removed, covers the suction control vent (completely or partially) to draw the tissue into the aspiration window, then depresses the motor control button. The tissue is mechanically broken-up and evacuated via vacuum into the collection receptacle. The wire loops stop rotating when the motor control button is released. The mechanical break-up of tissue can only occur inside of the wand.

9) COMPARISON TO PREDICATE

Comparing the modified devices to the predicate devices shows that the primary difference is the rate of aspiration. The modified devices have aspiration rates that are faster than those of the predicate. This is due to the larger diameter wands that are less restrictive to flow. Since lower aspirations rates represent worse case performance, no new questions of safety and effectiveness are introduced by the modified devices.

10) CONCLUSION

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