August 12, 2020

Rebound Therapeutics
Ms. Naomi Gong
VP of Regulatory Affairs
13900 Alton Parkway, Suite 120
Irvine, California 92618

Re: K201637
Trade/Device Name: AURORA Evacuator +Coag
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 15, 2020
Received: June 16, 2020

Dear Ms. Gong:

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)*
K201637

Device Name
AURORA Evacuator +Coag

Indications for Use *(Describe)*
The AURORA Evacuator +Coag is a powered instrument with a handpiece intended for removal of soft tissue and fluids, and coagulation of tissue under direct visualization. Types of direct visualization may include laparoscopic, pelviscopic, endoscopic, percutaneous, and open.

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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510(k) Summary

SUBMITTER

Rebound Therapeutics
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Date Prepared: August 11, 2020

DEVICE

Name of Device: AURORA Evacuator +Coag
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting & Coagulation Device & Accessories
Regulatory Class: II
Product Code: GEI

PREDICATE DEVICE

Primary: K960455, Bipolar Suction Coagulator, Kirwan Surgical Products
Reference: K190075/K180372, AURORA Evacuator, Rebound Therapeutics

DEVICE DESCRIPTION

The subject device, AURORA Evacuator +Coag, is provided sterile, for single use only. It is a disposable, handheld, battery powered instrument that combines the ability to remove fluids and soft tissue, apply bipolar energy for the coagulation of tissue, and apply irrigation directly to clear the surgical site during minimally invasive surgical procedures.

It consists of a wand and handle with connection ports for a bipolar electrode cable, vacuum source (for aspiration) and irrigation line. At the distal tip of the wand, a side aspiration window with an internally rotating whisk is provided to break up and aspirate soft tissue and fluids. The battery and motor that powers the whisk is contained in the device handle. Bipolar electrodes are located at the distal tip of the wand and can be activated to coagulate tissue when connected to an electrosurgical generator. When desired, an irrigation line may be connected to the handle and saline can be delivered to clear the surgical field as a procedural aid.

Bipolar electrosurgical generator/cables, vacuum source, and irrigation source are not provided with the device. Prior to use, the device is to be connected to electrosurgical generator, external vacuum source (i.e. operating room suction) and irrigation source (i.e. drip).

A green power indicator light is located on the top portion of the handle to show that power is available to the device. A suction control vent for the user to control vacuum pressure and a button for activating the whisk are located conveniently on the handle.

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INDICATIONS FOR USE

The AURORA Evacuator +Coag is a powered instrument with a handpiece intended for removal of soft tissue and fluids, and coagulation of tissue under direct visualization. Types of direct visualization may include laparoscopic, pelviscopic, endoscopic, percutaneous, and open.

COMPARISON TO PREDICATE

The subject device, the AURORA Evacuator +Coag, are new models of the reference device, AURORA Evacuator, to which bipolar electrodes have been added for the coagulation of tissue. The subject device incorporates the same bipolar technology to perform the coagulation of tissue as the primary predicate device.

Comparison to Predicate/Reference Devices

Description	Subject Device	Predicate Device	Reference Device
Device	**AURORA Evacuator +Coag**	**Kirwan Bipolar Suction Coagulator**	**AURORA Evacuator**
510(k)	K201637	K960455	K190075/K180372
Product Code	GEI (21CFR 878.4400)	Same	Same
Indications for Use	The AURORA Evacuator +Coag is a powered instrument with a handpiece intended for removal of soft tissue and fluids, and coagulation of tissue under direct visualization. Types of direct visualization may include laparoscopic, pelviscopic, endoscopic, percutaneous, and open.	Disposable device designed to be used in soft tissue surgical procedures that require slow to rapid fluid evacuation and lower energy output for the coagulation of the tissue i.e. neurosurgery, endoscopic, sinusoidal, ENT, OB-GYN and plastic surgery.	The AURORA Evacuator with coagulation 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.
Technological characteristics - Summary	1. Removal of fluid by suction lumen (wall vacuum source) ▪ Rotating whisk incorporated in suction lumen at distal tip for removal of soft tissue (i.e. blood clot) 2. Bipolar electrodes at distal tip for coagulation of tissue 3. Irrigation lumen for saline drip	1. Removal of fluid by suction lumen (wall vacuum source) 2. Same as Subject device 3. N/A	1. Same as Subject device 2. N/A 3. N/A

510(k) Summary

Description	Subject Device	Predicate Device	Reference Device
Aspiration Characteristics			
Wand Material Working length OD	 304 SS 7 – 13 cm 12 F	 Copper alloy 14 -19 cm 8 – 15 F	 Same as Subject device 7 - 13 cm 9 – 11 F
Aspiration Window	Window at side of distal end	At distal end	Same as Subject device
Whisk	Located internal at aspiration window Flat member with notches 301 SS	N/A (Evacuation through suction only)	Same Two wire loops Nitinol
Power Source for Motor	Battery located in handle – one 6V Alkaline	N/A	Batteries located in handle – two AAA 1.5V Alkaline
Vacuum source (external)	Connect to barb on device handle to Operating Room suction (i.e. wall)	Same	Same
Vacuum control	Suction vent on handle that is fingertip controlled	Same	Same
Bipolar Electrodes Characteristics			
Electrodes Type Shape Material Insulation Rated Voltage	 Bipolar 2 rectangular components Silver Polyphenylsulfone 450 Vp-p	 Same 2 concentric tubes Copper alloy High temp polymer 1200 V p-p	 N/A
Power Source for Bipolar electrodes	Cable to electrosurgical generator (external) connected to AC mains. - Cable and Electrosurgical generator are not provided	Same	N/A
Irrigation			
Irrigation lumen with luer connector	Capability for saline drip irrigation delivery to distal tip. Connection on device handle to saline bag with line clamp for clinician to control irrigation rate.	N/A	N/A
Other Characteristics			
Use	Single use, sterile	Same	Same
Sterilization Method	Ethylene oxide gas SAL 10^{-6}	Irradiation Same	Same as Subject device Same
Biocompatibility	ISO 10993-1	Same	Same

Description	Subject Device	Predicate Device	Reference Device
EMC, Immunity, and Electrical Safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	Same Same Same	Same Same N/A
Accessories	None	Same	Same

SUMMARY OF NON-CLINICAL TESTING

The following testing was conducted to demonstrate the safe and effective use of the AURORA Evacuator +Coag:

- Biocompatibility Testing per ISO 10993-1, including Cytotoxicity (MEM Elution), Sensitization (Kligman Maximization), Irritation (Intracutaneous Injection), Systemic Toxicity (Systemic Injection), Materials Mediated Pyrogenicity
- Electrical Safety and Enclosure Protection per IEC 60601-1 and IEC 660601-2-2
- Emissions and Immunity per IEC 60601-1-2
- Particulate Testing per USP <788>
- Sterilization per ISO 11135-1 to validate a SAL of 10^{-6}
- Packaging and Shelf-life per ISTA 2A and ASTM F1980-16
- Verification of product specifications including materials, multiple bonds evaluations, physical characteristics, performance characteristics and tissue thermal effects (coagulation of tissue).

  Ex-vivo tissue studies (porcine heart, liver, and kidney) demonstrated comparable thermal damage effect (coagulation zone) using the bipolar electrodes when compared with the primary predicate under the same test parameters and conditions. Thermal damage as a function of temperature and time with the 3 tissue types also supported comparability.
- Validation of product performance using surrogate soft tissue materials and fluids.

CONCLUSION

Based upon the performance data provided in this submission and comparing indicated use, design, materials, principle of operation and overall technological characteristics, the AURORA Evacuator +Coag has been determined to be substantially equivalent to the predicate device.

The ex-vivo tissue studies (porcine heart, liver, and kidney) demonstrated comparable thermal damage effect (coagulation zone and tissue temperature studies) using the bipolar electrodes when compared with the primary predicate under the same test parameters and conditions.