January 18, 2018

Rebound Therapeutics Corporation
Jane Metcalf
Vice President Regulatory Affairs
13900 Alton Parkway
Irvine, California 92618

Re: K182211
Trade/Device Name: Aurora Surgiscope System
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG, GZT
Dated: August 13, 2018
Received: August 15, 2018

Dear Jane 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. 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,

Matthew C. Krueger -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K182211

Device Name
Aurora Surgiscope System

Indications for Use *(Describe)*

The Aurora Surgiscope System is intended for use in endoscopic neurosurgery and pure neuroendoscopy (i.e. ventriculoscopy) for visualization, diagnostic and/or therapeutic procedures such as ventriculostomies, biopsies and removal of cysts, tumors and other obstructions.

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

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Phone: (949) 305-8111
www.reboundtx.com
Contact Person: Jane Metcalf
Date Prepared: August 13, 2018

2) DEVICE

Name of Device: Aurora Surgiscope System
Common or Usual Name: Neurological Endoscope
Classification Names: Neurological endoscope, Self-retaining retractor for neurosurgery
Classification Numbers: 882.1480, 882.4800
Regulatory Class: II
Product Code: GWG, GZT

3) PREDICATE DEVICE

Primary Predicate: Aesculap MINOP System, K983365
Secondary Predicate: NICO Brain Port, K120691

4) DEVICE DESCRIPTION

The Aurora Surgiscope System consists of two components: A sterile, single use, neurological endoscope called the Aurora Surgiscope and a non-sterile, reusable control unit called the Image Control Box (ICB).

The Aurora Surgiscope includes the following parts:

- Sheath
- Camera
- LED (Light Emitting Diodes)
- Sheath Cable
- Obturator

The Sheath is fabricated from plastic and shaped like a hollow cylinder. It acts as both the insertion portion and instrument channel of the endoscope. LEDs are embedded into the Sheath's distal end for illumination. The Sheath's proximal end incorporates a larger diameter plastic ring with a fixation tab. The Camera is rigidly attached to the plastic ring and positioned to produce a forward view of the surgical site. The Sheath's electronics are connected to the ICB by a flexible shielded cable. The cable exits from the rear of the Camera housing and connects to the ICB during system set-up. The Obturator is pre-loaded into the Sheath. Its distal tip is fabricated from clear plastic and is conical

shaped. It has a plastic handle at the proximal end to facilitate removal. A cannulated steel post connects the Obturator tip and handle.

The Image Control Box is supplied with two cables; one for power and the other for connection to a 3rd party external HD Monitor. The ICB delivers power to the LEDs and Camera, transfers the video image to the HD Monitor, and allows a user to turn knobs that digitally adjust image quality and orientation.

5) INDICATIONS FOR USE

The Aurora Surgiscope System is intended for use in endoscopic neurosurgery and pure neuroendoscopy (i.e. ventriculoscopy) for visualization, diagnostic and/or therapeutic procedures such as ventriculostomies, biopsies and removal of cysts, tumors and other obstructions.

6) SUMMARY OF NON-CLINICAL TESTING

The following testing was conducted to demonstrate the safe and effective use of the Aurora Surgiscope System 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, IEC 60601-2-18 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
- Simulated use testing
- Design verification testing
- Software and System Verification and Validation

7) TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE

	SUBJECT DEVICE Aurora Surgiscope System	PRIMARY PREDICATE Aesculap MINOP System
System Components		
Trocar	The device is a Trocar with OD ≤ 11.5mm One (1) channel The channel provides visual access for the camera, and working access for instruments, including suction and irrigation. An overflow channel is not required in the Surgiscope. One (1) Obturator	Trocar Model FF399R, OD 6mm 4 channels: • Scope - 2.8mm • Working - 2.2mm • Irrigation - 1.4mm • Overflow - 1.4mm 4 Obturators
Endoscope (Telescope)	The device is an Endoscope Direction of View - 0° Shaft Diameter ≤ 11.5mm Shaft length – 130mm, 100mm, 70mm for each of 3 models respectively	Model PE184A is an Endoscope Direction of View - 0○ Shaft Diameter – 2.7mm Shaft length 180 mm

	SUBJECT DEVICE	PRIMARY PREDICATE
	Aurora Surgiscope System	**Aesculap MINOP System**
Light Source	LED lights incorporated into distal end of device LEDs powered by Control Unit	Model OP940 – LED Source Model OP - 923 Fiber Optic Cable Control Unit
Camera	Integrated Camera Control Unit	Camera Model # PV 462 Control Unit Model # PV460
Monitor	Not supplied	PV 646 24" Full HD LCD Monitor
Principles of Operation		
Access to the surgical site	Aurora Surgiscope's Sheath and Obturator components used to access the surgical site The Obturator extends 10mm (-1mm, +2mm) beyond distal end of Sheath	Trocar and Obturator used to access the surgical site. MINOP telescope inserted into the Trocar. The Obturator is flush with Trocar's distal end.
Image Acquisition	Image acquisition is achieved through an integrated camera external to the surgical opening	Image acquisition is achieved through a connected camera external to the surgical opening
Image Processing	Image is digitally processed	Image is digitally processed
Image Display	External monitor connection	External monitor connection
Illumination	Illumination is achieved via direct transmission using an LED light source incorporated into the device.	Illumination is achieved via fiber optic transmission using an external light source.
Visualization	CMOS, color, video, camera with proprietary software that is incorporated into proximal end of the device and controlled via control unit.	Separately supplied HD 1080 p60 camera system consisting of CCU, camera head cable and zoom coupler. Camera head mounted onto scope and controlled by control unit. Alternatively, direct view through eye-piece on the Endoscope Trocar.
Working Channel	One	One
Accessories	Power Supply, Display Cable	Cables and dedicated instruments; e.g. reusable scissors, biopsy forceps, fixation and dissection forceps.
Other		
Biocompatibility	Demonstrated based on externally communicating device in direct contact with tissue/bone/dentin for a limited duration	Demonstrated based on externally communicating device in direct contact with tissue/bone/dentin for a limited duration
Materials	Plastic	Stainless Steel
Depth Markings	Yes	Yes
Inner Diameter	8 mm	≤ 2.7mm
Working Lengths	7cm, 10cm and 13cm	18cm
Obturator Tip	Conical Shaped	Rounded
Use and How Supplied	Endoscope - Single Use, Sterile Control unit – Reusable, Non-sterile	Endoscope – Reusable, Non-sterile Control units – Reusable, Non-sterile

8) 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 Surgiscope System has been determined, by Rebound Therapeutics Corporation, to be substantially equivalent to the primary predicate.