October 27, 2023

Rebound Therapeutics Corporation
Timothy Connors
Senior Manager, Regulatory Affairs
13900 Alton Parkway, Suite 120
Irvine, California 92618

Re: K232618
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 28, 2023
Received: August 29, 2023

Dear Timothy Connors:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2023.10.27 15:14:14 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232618

Device Name
Aurora Surgiscope System

Indications for Use *(Describe)*
The Aurora Surgiscope System is intended for use in neurosurgery and 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Aurora Surgiscope System
Traditional 510(k)

510(k) Summary (per 21 CFR 807.92)

Submitter Information	
Applicant	Rebound Therapeutics Corporation 13900 Alton Parkway, Suite 120 Irvine, CA 92618
Owner/Operator	Integra LifeSciences 1100 Campus Road Princeton, NJ 08540
Applicant Contact	Timothy Connors, RAC Senior Regulatory Affairs Manager Phone: 609-325-7161 (cell) E-mail: timothy.connors@integralife.com
Date Prepared	August 28, 2023
Subject Device Information	
Name of Device	Aurora® Surgiscope® System
Regulation Number	21 CFR 882.1480, 21 CFR 882.4800
Regulation Name	Neurological endoscope; Self-retaining retractor for neurosurgery
Regulatory Class	II
Product Code	GWG; GZT
Predicate Device	Aurora Surgiscope System K201840
Reference Device	Aurora Surgiscope System K191861
Device Description	
The Aurora Surgiscope System consists of two components: (1) a sterile, single use, sheath with integrated illumination LEDs and camera, with an obturator, and (2) a non-sterile, reusable control unit, Image Control Box (ICB). The sheath is intended to provide access to the surgical site by acting as the insertable portion of the device, as well as the instrument channel to accommodate other surgical tools. Depth markers are present along the length of the sheath for user reference.	

At the proximal end of the sheath is the imager, which comprises the following components: LEDs (light emitting diodes), camera (and optical components), and focus knob.

- The LEDs provide illumination to the surgical field by directing light down the sheath, along the instrument channel.
- The camera captures video image of the surgical field.

The proximal end of the sheath also contains a tab, which may be used to manually hold the device. To facilitate insertion of the sheath to the surgical site, an obturator is provided with the device. During insertion, the obturator is fully inserted into the sheath, and the entire unit is advanced to the desired location. The distal end of the obturator is conical in shape to minimize tissue damage. In addition, the proximal handle of the obturator is designed to accommodate various stereotactic instruments for neuronavigation. Once inserted, the obturator is removed. Two sterile, single use accessories optional for use are provided with the Aurora Surgiscope System: an Irrigation Device and 12 French Suction Device.

The ICB is a non-sterile device that provides three main functions in the Aurora Surgiscope System:

- To power the Surgiscope LEDs and camera
- To relay the video feed captured by the Surgiscope camera to a display monitor for real-time image visualization
- To allow the user to make adjustments to the displayed video feed (e.g., contrast, brightness), as well as vary the LED light output.

The user interface is a membrane keypad with buttons located on the ICB that can be depressed for image adjustment, such as zoom, contrast, brightness, and orientation. The ICB is supplied with two cables: A power cable for connection to an AC wall outlet, and a display cable for connection to a high definition surgical monitor.

Intended Use of the Device

The Aurora Surgiscope System is intended for use in neurosurgery and 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.

Summary of Technological Characteristics Compared to Predicate Device			
	Subject Device	**Predicate Device**	**Reference Device**
Indications For Use	The Aurora Surgiscope System is intended for use in neurosurgery and 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.	Same	Same, without "neurosurgery" included prior to "endoscopic neurosurgery"
Sheath	• OD = 11mm, ID = 8.4mm • Lengths: 70, 100 and 130mm • Incremental depth markings • With obturator (conical shape, rounded tip)	• OD = 16.2mm, ID = 11mm • Lengths: 60 and 80mm • Same • Same	• OD ≤ 11.5mm, ID = 8mm • Lengths: 70, 100 and 130mm • Same • Same
Materials	Methyl methacrylate ABS (Sheath), Polycarbonate (Tab), pad printing ink, hardner, and thinner	6061-T6 Aluminum (Sheath and tab) with bright dip and clear anodization, 17-7 PH stainless steel – passivated (retaining	Lustran ABS, PET, ColorCon No Tox Ink, plastic ring mount for camera assembly

		ring); cyanoacrylate adhesive	
Imager	The device incorporates and imaging system with camera and optics (lens, prism): • Direction of View: 0° • Depth of field = 0 to 3 cm	Same	Same
Light Source	2 LED lights, incorporated onto Imager, user can vary intensity level	4 LED lights, incorporated onto Imager, user can vary intensity level	6 LED lights, incorporated onto distal end of sheath, fixed intensity level
Camera	Integrated CMOS camera and electronics	Same	Same
Image Control Box	• Electronics (circuit boards, CPU with software control) • Keypad buttons for image adjustment by user	• Same • Same	• Equivalent • Same
Sterile Accessories	• Irrigation device • 12 French Suction device (Optional for use)	N/A	N/A
Non-sterile Accessories	• Power supply and cable • Display cable • Display cable adaptor	Same	Same, without display cable adaptor
Display Monitor	Not supplied	Same	Same
Access to Surgical Site	Sheath and obturator used to access the surgical site.	Same	Same

	The obturator extends 10mm beyond distal end of the sheath.		
Single Working Channel	Removal of obturator reveals working channel which provides visual access for camera and working access for instruments including suction, bipolar, irrigation and tissue removal devices.	Same	Same
Image Acquisition	Image acquisition is achieved through an integrated camera.	Same	Same
Image Processing	Image processing is achieved through an integrated camera.	Same	Same
Image Display	Image is displayed via external display monitor connection.	Same	Same
Illumination	Illumination is achieved via direct LED light sources incorporated into the device.	Same	Same
Visualization	CMOS, color, video, camera (with software) incorporated at proximal end of the device and controlled via ICB.	Same	Same
Biocompatibility	Surgiscope: demonstrated based on externally	Same	Same

	communicating device in direct contact with tissue/bone/dentin for a limited duration.		
Use / How Supplied	Surgiscope: single use, sterile Image Control Box: reusable, non-sterile	Same	Same
Sterilization Method	Surgiscope: ethylene oxide gas	Same	Same

Summary of Non-clinical Testing

The following testing was conducted to demonstrate substantial equivalence to the predicate device in terms of safety and effectiveness.

Biocompatibility testing

The Aurora Surgiscope System is intended to come into direct contact with human tissue during use and was evaluated and tested per the recommendations of the FDA Guidance FDA Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."* The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemolysis (Indirect)

The patient contacting components are categorized as:

- Category: External communicating device
- Contact: Tissue/bone/dentin
- Contact Duration: Limited (≤ 24 hours)

The ICB and non-sterile accessories are not intended to have direct or indirect patient contact.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the fully assembled Aurora Surgiscope System. The system complies with the applicable clauses of IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-18.

Software verification and validation testing

Software testing was conducted and documentation provided as recommended by the FDA Guidance *Content of Premarket Submissions for Device Software Functions.* The software documentation included in the submission was per the Enhanced Documentation Level recommendations.

Mechanical and other testing

- Bench testing: dimensional, imaging (visualization, image resolution, on-axis and off-axis resolution), field of view, system latency, camera resolution, temperature of contact points, illumination, tensile strength between components
- Compatibility: instrument use in instrument channel
- Particulate testing per USP <788>
- Sterilization validation to validate a Sterility Assurance Level of 10^{-6}
- Package integrity and shelf life testing

Conclusion

Based upon the performance data provided in this submission and comparing indications for use, design, materials, principle of operation and overall technical characteristics, the Aurora Surgiscope System has been determined to be substantially equivalent to the predicate device.