November 4, 2020

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

Re: K201840
Trade/Device Name: Aurora Surgiscope System (Surgiscope), Aurora Surgiscope System (Image Control Box)
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG, GZT
Dated: July 1, 2020
Received: July 2, 2020

Dear Naomi 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,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K201840

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.

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510(k) Summary
(K201840)

SUBMITTER

Rebound Therapeutics
13900 Alton Parkway, Suite 120
Irvine, CA 92618

Contact Person: Naomi Gong, RAC
Vice President of Regulatory Affairs
Telephone: (949) 523-6510
Email: naomi.gong@integralife.com
Date Prepared: November 4, 2020

DEVICE

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, Rebound Therapeutics, K191861
NICO BrainPath, NICO Corp, K172433 (Reference device)

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 serves as the location for the fixation arm to hold/fix 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.

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.

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.

SUMMARY OF NON-CLINICAL TESTING

The following testing was conducted to demonstrate the safe and effective use and substantial equivalence to the predicate device.

(1) 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 requirements and recommendations of the FDA Guidance, "Use of 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 (MEM Elution)
-Sensitization (Kligman Maximization)
-Irritation (Intracutaneous Injection)
-Systemic Toxicity (Systemic Injection)
-Hemolysis (In direct)
-Materials Mediated Pyrogenicity

The sheath with LEDs and camera portion is considered a tissue contacting and externally communicating for a duration of less than 24 hours. The ICB is not intended to have direct or indirect patient contact and therefore biocompatibility for it was not evaluated.

(2) Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the AURORA Surgiscope System consisting of both components, sheath with LEDs and camera, and the ICB. The system complied with the IEC 60601-1-1, IEC 60601-1-2, and IEC 60601-2-18.

(3) Software verification and validation testing

Software verification and validation testing were conducted and documentation was provided as recommended by the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software for this device was considered as a major level of concern, since a failure or latent flow in the software could directly result in a serious injury or death to the patient or operator.

(4) Mechanical and other testing

- Bench testing – dimensional, imaging (visualization, resolution, etc.), illumination, tensile strength between components
- Simulated use testing – clinician evaluation
- Compatibility – instrument use in instrument channel, use with other devices (i.e., bipolar electrosurgical)
- 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

COMPARISON OF TECHNICAL CHARACTERISTICS TO PREDICATE DEVICE

	PREDICATE Device	**SUBJECT Device**
	Aurora Surgiscope System (K191861)	**Aurora Surgiscope System**
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.	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.
Sheath	▪ OD ≤ 11.5mm, ID = 8 mm ▪ Lengths = 70, 100, 130 mm ▪ Incremental depth markings ▪ Single working channel ▪ With obturator (conical shape, rounded tip)	▪ OD = 16.2 mm, ID = 11 mm ▪ Lengths = 60 and 80 mm ▪ Same ▪ Same ▪ Same
Materials	Sheath: ABS, PET, adhesives, white ink depth marker Obturator: Polycarbonate, 304 SS, ABS, adhesives	Sheath: Aluminum, adhesives Obturator: Same
Imager	The device incorporates an imaging system with camera and optics (lens, prism): Direction of View = 0° Depth of field = 0 to 3 cm	Same
Light Source	6 LED incorporated into inner dia. of sheath near distal end – fixed intensity level	4 LEDs incorporated into Imager (proximal end of sheath) – user can vary intensity level
Camera	Integrated CMOS camera and electronics	Same
Image Control Box (control unit)	▪ Electronics (Circuit boards, CPU with software control) ▪ Keypad buttons for image adjustment by user	▪ Equivalent ▪ Same
Other (accessories)	Power supply and cable Display cable	Same
Display Monitor	Not supplied	Same
Access to the surgical site	Sheath and Obturator used to access the surgical site. The Obturator extends 10mm beyond distal end of sheath	Same
Single working channel	Removal of obturator reveals working channel which provides visual access for camera and working access for instruments including suction, bipolar, and irrigation.	Same
Image acquisition	Image acquisition is achieved through an integrated camera	Same
Image processing	Image is digitally processed by control unit	Same
Image display	External display monitor connection	Same
Illumination	Illumination is achieved via direct LED light sources incorporated into the device.	Same
Visualization	CMOS, color, video, camera (with software) incorporated at proximal end of the device and controlled via control unit.	Equivalent

	PREDICATE Device	**SUBJECT Device**
	Aurora Surgiscope System (K191861)	**Aurora Surgiscope System**
Biocompatibility	Surgiscope: Demonstrated based on externally communicating device in direct contact with tissue/bone/dentin for a limited duration	Same
Use and how supplied	Surgiscope: single use, sterile ICB (control unit): reusable, non-sterile	Same
Sterilization Method	Surgiscope: Ethylene oxide gas	Same

The NICO BrainPath device (K172433) is included as a reference device because its sheath diameter is comparable and its sheath/obturator has the same intended use to access the surgical field during neurosurgery.

CONCLUSION

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