April 9, 2025

Integra LifeSciences Corporation
Rebecca Odulio
Senior Regulatory Affairs Specialist
1100 Campus Rd.
Princeton, New Jersey 08540

Re: K250752
Trade/Device Name: AURORA Surgiscope System (ASX15/60); AURORA Surgiscope System (ASX15/80)
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG, GZT
Dated: March 12, 2025
Received: March 12, 2025

Dear Rebecca Odulio:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2025.04.09 13:04:06 -04'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250752

Device Name
AURORA Surgiscope System (ASX15/60);
AURORA Surgiscope System (ASX15/80)

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) #:

510(k) Summary

Prepared on: 2025-03-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Integra LifeSciences Corporation
Applicant Address	1100 Campus Rd. Princeton NJ 08540 United States
Applicant Contact Telephone	812-955-9955
Applicant Contact	Mrs. Rebecca Odulio
Applicant Contact Email	rebecca.odulio@integralife.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	AURORA® Surgiscope® System (ASX15/60); AURORA® Surgiscope® System (ASX15/80)
Common Name	Neurological endoscope
Classification Name	Endoscope, Neurological
Regulation Number	882.1480
Product Code(s)	GWG, GZT

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K201840	AURORA Surgiscope System	GWG

Device Description Summary

21 CFR 807.92(a)(4)

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. The proximal end of the Sheath also incorporates a Tab, which serves as the location for fixation arm to hold the device.

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 working channel.
- The camera captures videos of the surgical field.
- The focus knob allows the user to adjust the focus of the camera to obtain the desired image quality.

To facilitate insertion of the Sheath into the surgical site, an Obturator is provided with the device. During device insertion, the Obturator is fully inserted into the Sheath, and the entire AURORA Surgiscope is advanced to the desired surgical location. The distal end of the Obturator is conical in shape to minimize tissue damage during device insertion. In addition, the proximal handle of the Obturator is designed to accommodate various stereotactic instruments for neuronavigation, which can further aid in device placement. The Obturator is removed after insertion.

The ICB is a non-sterile device that provides three main functions in the AURORA Surgiscope System:
- To power the LEDs and camera of the AURORA Surgiscope.

• To relay the video feed captured by the AURORA Surgiscope camera to a connected Medical Grade Surgical Monitor for real-time image visualization.
• To allow the user to make adjustments to the displayed video feed (e.g., contrast, brightness), and to vary the light output of the LEDs.

The user interface is a membrane keypad with buttons located on the ICB that can be depressed for image adjustment, such as zoom, contrast, and brightness. The connection ports for the AURORA Surgiscope, Medical Grade Surgical Display Monitor, and Power are located on the side of the ICB, along with the ON/OFF switch.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The intended use and indications for use statement for the subject AURORA Surgiscope System are the same as compared to the predicate device (K201840).

Technological Comparison 21 CFR 807.92(a)(6)

The subject AURORA Surgiscope System and predicate device (K201840) have the same technological characteristics. The only difference is the Obturator handle design modification.

The proposed modified design includes the addition of two bridge features over the post channel on the obturator handle to improve the strength of the connection between the handle and post. The subject device Obturator design is nearly identical as compared to the predicate device (K201840).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical testing was performed to ensure the safety and efficacy of the subject AURORA Surgiscope System device by confirming that the device meets functional requirements following 2X EO sterilization, environmental and transit conditioning, and the equivalent of the 1 year claimed shelf-life.

No clinical test/studies were required or performed as all conducted performance tests appropriately support a determination of substantial equivalence compared with the predicate device (K201840).