August 2, 2023

Activ Surgical Inc.
Nicholas Child
Senior Manager, Quality Engineering
30 Thomson Place
Boston, Massachusetts 02110

Re: K231344
Trade/Device Name: ActivSight Intraoperative Imaging System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OWN
Dated: May 5, 2023
Received: May 9, 2023

Dear Nicholas Child:

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,

Jessica Carr -S

Jessica Carr, PhD
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231344

Device Name
ActivSight Intraoperative Imaging System

Indications for Use *(Describe)*
The ActivSight Intraoperative Imaging System (ActivSight) is intended to provide real-time endoscopic fluorescence and near infrared imaging. ActivSight enables surgeons to visually assess vessels, blood flow, and related tissue perfusion using fluorescence and near infrared imaging, and at least one of the major bile ducts (cystic duct, common bile duct, or common hepatic duct) using fluorescence, all during minimally invasive surgery.

Fluorescence imaging of biliary ducts with ActivSight is intended for use with standard of care white light, and when indicated, intraoperative cholangiography. The device is not intended for stand-alone use for biliary duct visualization.

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.

5. 510(k) Summary

This 510(k) summary is being submitted in accordance with 21 CFR 807.92

A. Submitter's Information

Name:	Activ Surgical, Inc.
Address:	30 Thomson Place Boston, MA 02210
Contact:	Nicholas Child
Phone:	(617) 957-1434
Email:	nchild@activsurgical.com
Date Prepared:	July 28, 2023

B. Device Information

Trade/Proprietary Name:	ActivSight Intraoperative Imaging System
Common/Usual Name:	Confocal Optical Imaging
Classification Name:	Endoscope and Accessories, 21 CFR 876.1500
Class:	II
Product Codes:	OWN

C. Predicate Device

Activ Surgical, Inc.

ActivSight Intraoperative Imaging System, K203550

D. Device Description

The ActivSight Intraoperative Imaging System (ActivSight) is an accessory to existing commercial surgical laparoscope systems, including cameras and video processor units. ActivSight provides real-time endoscopic fluorescence and near-infrared imaging. These imaging features allow surgeons to visually assess vessels, blood flow, and tissue perfusion (using fluorescence and near-infrared imaging), and to visually assess at least one of the major bile ducts (cystic duct, common bile duct, or common hepatic duct) using fluorescence. Fluorescence imaging is enabled through use of any commercially available Indocyanine Green (ICG). These visualization features are available for surgeons to use during minimally invasive surgery. ActivSight is intended to be used in a surgical environment.

E. Intended Use

The ActivSight Intraoperative Imaging System (ActivSight) is intended to provide real-time endoscopic fluorescence and near infrared imaging. ActivSight enables surgeons to visually assess vessels, blood flow, and related tissue perfusion using fluorescence and near infrared imaging, and at least one of the major bile ducts (cystic duct, common bile duct, or common hepatic duct) using fluorescence, all during minimally invasive surgery.

Fluorescence imaging of biliary ducts with ActivSight is intended for use with standard of care white light, and when indicated, intraoperative cholangiography. The device is not intended for stand-alone use for biliary duct visualization.

F. Summary of Technological Characteristics Compared to Predicate

The modified device and the predicate device are the same device and are identical in intended use and technology. The modified device instructions for use provides for a new method of sterilization prior to each use.

G. Non-Clinical Testing

To support substantial equivalence of the modified device to the predicate device, the following testing was performed:

- Sterilization efficacy according to ANSI/AAMI/ISO14937:2009/(R)2013, Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices.

  Sterilization efficacy testing validated that the Imaging Modules achieved a Sterility Assurance Level (SAL) of 10-6 when sterilized using the following sterilization methods:

Vaporized Hydrogen Peroxide (VHP) Cycles
STERRAD NX (Standard & Advance Cycle) NX AllClear (Standard & Advance Cycle) 100NX (Express & Standard Cycle) 100NX AllClear (Express & Standard Cycle)
Steris V-PRO s2 (Non-Lumen, Lumen, Flexible, or Fast cycle) V-PRO 60 (Non-Lumen, Lumen, or Flexible cycle) V-PRO maX (Non-Lumen, Lumen, or Flexible cycle) V-PRO maX 2 (Non-Lumen, Lumen, Flexible, or Fast Non-Lumen cycle)

- In addition, functional testing confirmed that reprocessing of the modified device does not impact the functional reliability or performance of the modified device over multiple reprocessing cycles.

The results of the testing support the claim that the ActivSight Intraoperative Imaging System is safe and effective for its intended use, when used according to the Instructions for Use.

H. Clinical Testing

The proposed modification did not require clinical testing to demonstrate substantial equivalence.

I. Conclusion

Based on the information provided in this premarket notification and based on a comparison to the indications for use, performance testing, and technological characteristics of the predicate, the proposed ActivSight Intraoperative Imaging System does not raise new questions of safety and efficacy, and is substantially equivalent to the ActivSight Intraoperative Imaging System**.**