Activ Surgical, Inc.
Matthew King
Director of Regulatory Affairs and Quality Assurance
840 Summer Street
Boston, Massachusetts 02127

April 8, 2021

Re: K203550
Trade/Device Name: ActivSight Intraoperative Imaging System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ, OWN, DPT,
Dated: March 8, 2021
Received: March 9, 2021

Dear Matthew King:

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,

Neil R.P. Ogden

Digitally signed by Neil R.P. Ogden
Date: 2021.04.08 19:43:42 -04'00'

Neil R.P. Ogden
Assistant Director, THT4A4
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203550

Device Name
ActivSight

Indications for Use *(Describe)*

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.

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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"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) SUMMARY (21 CFR 807.92)

1. General Information

Submitter Name:	Activ Surgical, Inc.
Submitter Address:	840 Summer Street, Suite 108 Boston, MA 02127
Contact Person:	Matthew King Director of Regulatory Affairs and Quality Assurance Activ Surgical, Inc.
Contact Information:	Email: mking@activsurgical.com Phone: 603-459-9755 Fax: 617-977-0992
Submission Type	Traditional 510(k)
Date Prepared	December 4, 2020

2. Proposed Device

Proprietary Name	ActivSight Intraoperative Imaging System
Device Common Name	Light Source, Imaging Module, Light Cable
Device Model Number	450-00001
Device Classification Name	Confocal Optical Imaging
Regulation Number	21 CFR 876.1500
Product Code	OWN
Device Classification	II
Review Panel Premarket Review	General and Plastic Surgery General and Surgery Devices (DHT4A)

3. Predicate Device and Reference Device

	Predicate Device	**Reference Device**
Proprietary Name	Stryker Infrared Fluorescence (IRF) Imaging System	Perimed PeriCam PSI
510(k) Number	K142310	K120884
Device Classification Name	Confocal Optical Imaging	Extravascular blood flow probe
Regulation Number	21 CFR 876.1500	21 CFR 870.2120
Product Code	OWN	DPT
Device Classification	II	II

4. 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.

ActivSight consists of the following reusable components:

- **ActivSight Imaging Module**, consisting of optics and sensing electronics. The imaging module attaches physically between the third-party laparoscope and the third-party imaging system camera. Reprocessing of this component requires cleaning and disinfection between uses.
- **ActivSight Light Engine**, equipment consisting of system electronics that provide laser fluorescence and near-infrared illumination, processing of video input from both the third-party Camera Control Unit (CCI) and the ActivSight Imaging Module, and outputs video to the surgical monitor. This component does not require reprocessing between uses.
- **ActivSight Light Cable,** component consisting of a Y-shaped bifurcated light cable that connects to the third party white-light source, the ActivSight Light Engine, and the third party laparoscope light post (providing white-light illumination of the surgical site through the laparoscope). Reprocessing of this component requires cleaning and steam sterilization.
- **ActivSight Sterilization Tray,** stainless-steel sterilization tray designed to properly secure the ActivSight Light Cable for disinfection and sterilization. Reprocessing of this component is accomplished in its use- cleaning and steam sterilization.

ActivSight consists of the following disposable components:

- **ActivSight Sterile Drape,** a sterilized plastic drape that is provided for each use to provide a sterile barrier between the imaging module and the patient.
- **ActivSight Calibration Target,** a sterilized paper imaging target containing a checkerboard pattern for calibration of the ActivSight imaging module prior to each use of the device.

5. Indications for 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.

6. Performance Data

Safety and performance of the ActivSight Intraoperative Imaging System has been evaluated and verified in accordance with design specifications and applicable performance standards, including risk management, basic safety and essential performance, electromagnetic disturbances, human factors and usability, software lifecycle processes, safety of laser products. Activ Surgical has performed design validation in an animal study, comparatively visualizing blood flow and perfusion in specific structures with both ActivSight Perfusion (speckle laser) and ActivSight ICG (fluorescence) modes against the predicate's ICG mode. The following performance testing have also been conducted.

- Basic safety and essential performance testing completed in accordance with *IEC 60601-1:2005/R(2012) and A1:2012: Medical Electrical Equipment- Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD)*. Testing indicates that the proposed device conforms to this standard.

- Electrical safety and electromagnetic compatibility testing completed in accordance with *IEC 60601-1-2 Edition 4.0 2014-02 Medical Electrical Equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral Standard: Electromagnetic disturbances: Requirements and tests.* Testing indicates that the proposed device conforms to this standard.

- Human factors and usability testing completed in accordance with *IEC 62366-1: 2015 Medical Devices - Application of Usability Engineering to Medical Devices- Evaluation and reporting.* Testing indicates that the proposed device presents no unacceptable risk to the user during its intended use, and that the device conforms to this standard.

- Software development and software life cycle processes competed in accordance with *ANSI AAMI IEC 62304:2006/A1:2016 Medical Device Software- Software Life Cycle Processes, Evaluation, Testing, and Reporting.* Testing indicates that the proposed device conforms to this standard.

- Laser safety testing completed in accordance with *IEC 60825-1 Ed. 3.0 b:2014 Safety of Laser Products- Part 1: Equipment Classification and Requirements.* Testing indicates that the proposed device conforms to this standard.

- Safety of endoscopic equipment testing completed in accordance with *IEC 60601-2-18: Edition 3.0 2009-08 Medical Electrical Equipment- Part 2-18: Particular Requirements for the Basic Safety and Essential Performance of Endoscopic Equipment.* Testing indicates that the proposed device conforms to this standard.

The results of these studies demonstrate that the proposed device is as safe and effective as the predicate.

7. Substantial Equivalence

The ActivSight Intraoperative Imaging System (subject) is substantially equivalent to the Stryker® Infrared Fluorescence (IRF) Imaging System (predicate).

The subject device and predicate device have nearly identical Indications for Use. Both devices provide real-time endoscopic near-infrared fluorescence imaging during minimally invasive surgery. Both are indicated to enable surgeons visually assess blood flow, tissue perfusion, and at least one of the major bile ducts (cystic duct, common bile duct, or common hepatic duct). Fluorescence imaging of biliary ducts with both devices is intended for use with standard care white light, and when indicated, intraoperative cholangiography.

Both devices achieve their intended use through use of an FDA approved contrast drug agent (indocyanine green (ICG)).

Neither device is intended for stand-alone use for biliary duct visualization.

Differences between the two devices are ActivSight's capability to visualize blood flow and perfusion through speckle laser illumination, and ActivSight does not include laparoscopic equipment or a white light source. Laser speckle illumination is achieved through near-infrared laser diodes, imaging hardware, and imaging software that together display blood flow and perfusion without the aid of an imaging agent, such as ICG. ActivSight is interoperable with the existing laparoscopic equipment of the Stryker Infrared Fluorescence (IRF) Imaging System.

Table 5.1: Comparison to Predicate

	ActivSight Intraoperative Imaging System	**Stryker Infrared Fluorescence (IRF) Imaging System (K142310) - *Predicate***	**Perimed PeriCam PSI (K120884) – *Reference Device***
Intended Use	Confocal Optical Imaging (OWN)	Confocal Optical Imaging (OWN)	Probe, Blood-Flow, Extravascular (DPT)
Indications for 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.	The *Stryker® IRF Light Source* and *SafeLight Cable* are indicated for use to provide real-time endoscopic visible and near-infrared fluorescence imaging. The *Stryker® IRF Light Source* and *SafeLight Cable* enable surgeons to perform minimally invasive surgery using standard endoscope visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging. Fluorescence imaging of biliary ducts with the *Stryker® IRF Light Source* and *SafeLight Cable* are intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The devices are not intended for standalone use for biliary duct visualization.	The PeriCam PSI is intended for non-invasive two-dimensional imaging of peripheral tissue blood perfusion.

Technological Characteristics				
	ActivSight Intraoperative Imaging System		**Stryker Infrared Fluorescence (IRF) Imaging System (K142310) - *Predicate***	**Perimed PeriCam PSI (K120884) – *Reference Device***
	ActivSight Perfusion	**ActivSight ICG**		
Mode of Action	Laser Speckle	Fluorescence	Fluorescence	Laser Speckle
Contrast Agent	None	ICG	ICG	None

Information Presentation Format	Heatmap signal overlayed on red/green/blue (RGB) or heatmap signal only	Green Signal overlayed on red/green/blue (RGB)	Green signal overlayed on grayscale	Heatmap signal only with option for adjacent color image.
Light Source(s)	Coherent 852 nm laser	808nm laser	808nm laser	785nm laser
Light Source Power Rating	Class 3R out of Light Cable, class 1 out of scope	Class 3R out of Light Cable, class 1 out of scope	Class 1M	Class 1
Light Capture	IR sensitive camera	IR sensitive camera	IR sensitive camera	IR sensitive camera
Active Area of imaging sensor	1/2.9” CMOS, 4.98x3.74mm	1/2.9” CMOS, 4.98x3.74mm	1/3” CMOS, 4.8x3.6mm	Unknown

8. 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 ActivSight Intraoperative Imaging System is shown to raise no new questions of safety and efficacy, and is substantially equivalent to the Stryker Infrared Fluorescence (IRF) Imaging System.