November 29, 2022

SmartSurgN Incorporated
Jocelyn Long
Chief Compliance Officer
3150 Almaden Expressway Suite 252
San Jose, California 95118

Re: K213943/S001
Trade/Device Name: SmartSurgN Visualization System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OWN
Dated: September 30, 2022
Received: October 3, 2022

Dear Jocelyn Long:

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,

Jianting Wang -S

Jianting Wang
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)*
K213943

Device Name
SmartSurgN Visualization System

Indications for Use *(Describe)*
The SmartSurgN Visualization System is intended to provide realtime endoscopic visible (VIS) and real-time near-infrared (NIR) fluorescence imaging. Upon intravenous administration and use of an ICG consistent with its approved label the SmartSurgN Visualization System enables surgeons to perform minimally invasive surgery using standard endoscopic 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 SmartSurgN Visualization System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone 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.

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510(k) Summary - K213943

This summary statement is submitted in accordance with the requirements of CFR §807.92.

Submitter:	SmartSurgN Incorporated 1038 Leigh Ave, Suite 101B San Jose, CA 95126 USA
Contact:	Jocelyn Long jocelyn.long@smartsurgn.com 408-802-8586
Date of Preparation:	September 30, 2022
Device Identification:	Trade Name: SmartSurgN Visualization System Common Name: Endoscopic Video Imaging System Classification Name: Endoscope and Accessories
Product Code:	OWN
Regulation:	21 CFR part 876.1500
Predicate Devices:	Karl Storz Endoscopic ICG Imaging System (K152583) da Vinci Fluorescence Imaging Vision System (K124031)
Indications for Use:	The SmartSurgN Visualization System is intended to provide real-time endoscopic visible (VIS) and real-time near-infrared (NIR) fluorescence imaging. Upon intravenous administration and use of an ICG consistent with its approved label the SmartSurgN Visualization System enables surgeons to perform minimally invasive surgery using standard endoscopic 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 SmartSurgN Visualization System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

Device Description:

The SmartSurgN Visualization System is designed to provide real-time endoscopic visible (VIS) and real-time near-infrared (NIR) fluorescence imaging during minimally invasive surgery.

The SmartSurgN Visualization System is comprised of the following main components:

- EyeRSurgn Console with Camera Head
- IRLightSurgN Light Source
- 10mm ICG Laparoscope, 0° or 30°

The SmartSurgN Visualization System enables surgeons to perform minimally invasive surgery using standard endoscopic 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 SmartSurgN Visualization System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

During the use of the SmartSurgN Visualization System, the IRLightSurgN provides the light source for illumination of the surgical site. The IRLightSurgN is capable of outputting light in the visible light spectrum as well as in the near infrared spectrum. The user selects the image capture mode (Regular, IRMax, IRFlo, IRTrue) which determines the light spectrum used to capture imaging.

The IRLightSurgN is connected to the SmartSurgN Laparoscope using a commercially available fiber optic light cable. Additionally, the SSN Laparoscope connects to the EyeRSurgN Camera Head.

Images are acquired by the EyeRSurgN Camera Head and transmitted to the EyeRSurgN Console. Images are processed by the EyeRSurgN Console and outputted to a medical grade monitor.

The SmartSurgN Visualization System can be used with any medical grade monitor with a HDMI or 3G-SDI input connection.

The SmartSurgN Visualization System is intended to be used in conjunction with commercially available indocyanine green imaging (ICG) kits. ICG is a tricarbocyanine dye which fluoresces after excitation under near infrared light at 806 nm, permitting visualization of anatomical structures.

Technological Comparison Summary:

The SmartSurgN Visualization System utilizes the same technology as predicate devices Karl Storz Endoscopic ICG Imaging System (K152583) and Intuitive Surgical da Vinci Fluorescence Imaging Vision System (K124031).

The EyeRSurgN Console and EyeRSurgN Camera Head are substantially equivalent to the camera control unit and camera head in the Karl Storz Endoscopic Imaging System cleared for use in K152583.

The SmartSurgN Visualization System and the Karl Storz Endoscopic ICG Imaging System include rigid, rod lens scopes. Both systems offer scopes with 0° and 30° direction of view. The working length of the scopes in both systems is 31cm.

The IRLightSurgN Illuminator is substantially equivalent to the illuminator included in the Intuitive Surgical da Vinci Fluorescence Imaging Vision System and cleared for use in K124031.

The differences between the subject and predicate devices are:

- The inclusion of a fourth imaging sensor (IR CMOS) in the camera head. The Storz predicate has three imaging sensors.
- The SmartSurgN Visualization System Console output signal is HDMI at 4K60 in addition to SDI at 1080p60; the predicate device only has an output at SDI 1080p60.

The technological differences do not present any safety or effectiveness concerns.

Non-Clinical Performance Data:

The SmartSurgN Visualization System was successfully tested for performance, including a benchmark study with the predicate devices to assess endoscopic video imaging in visible and near-infrared conditions. Additionally, the SmartSurgN Visualization System was assessed in an animal model for simulated surgical environment feedback from clinicians. Testing was conducted for safety and electromagnetic compatibility IEC 60601-1 and 60601-1-2 per standards. Additional validations and testing were conducted for system software, ICG illumination, laser excitation, signal-to-noise ratio, biocompatibility, manual cleaning, sterilization and packaging.

Clinical Performance Data:	Clinical testing was not required to demonstrate substantial equivalence to the predicate devices.
Conclusion:	The SmartSurgN Visualization System is substantially equivalent to the Karl Storz Endoscopic ICG Imaging System (K152583) and Intuitive Surgical da Vinci Fluorescence Imaging Vision System (K124031) devices with regards to device design, materials, operating materials and performance characteristics. The use of the SmartSurgN Visualization System for its intended use does not raise new or different questions of safety or effectiveness.