



April 20, 2026

SmartSurgN Inc.
Jocelyn Long
Chief Compliance Officer
1038 Leigh Avenue
Suite 101B
San Jose, California 95126

Re: K242163
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: July 10, 2024
Received: July 24, 2024

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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

YAN FU-S

Digitally signed by YAN FU -S
Date: 2026.04.20 13:33:08
-04'00'

for Tanisha Hithe
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

Indications for Use

510(k) Number (if known)
K242163

Device Name
SmartSurgN Visualizaton 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K242163

This summary statement is submitted in accordance with the requirements of 21 CFR § 807.92

510 (k) Sponsor:	SmartSurgN Incorporated
Address	1038 Leigh Ave, Suite 101B San Jose, CA 95126 USA

Correspondence Person:	Jocelyn Long
Contact Information:	jocelyn.long@smartsurgn.com 408-802-8586

Date of Preparation:	April 15, 2026
Device Identification:	Trade Name: SmartSurgN Visualization System
Common Name:	Endoscopic Video Imaging System
Classification Name:	Endoscope and Accessories
Regulation Number:	21 CFR 876.1500
Product Code:	OWN
Regulatory Class	II

Indications for Use:	<p>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.</p>
Device Description	<p>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.</p> <p>The SmartSurgN Visualization System is comprised of the following main components:</p> <ul style="list-style-type: none"> • EyeRSurgN Console with PrizMCurgN Camera Head • IRLightSurgN Light Source

	<ul style="list-style-type: none"> • OptIcRSurgN 10mm ICG Laparoscope, 0° or 30° <p>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.</p> <p>During use, the IRLightSurgN Light Source provides visible and near-infrared illumination of the surgical site. The user selects the imaging mode (Regular, IRMax, IRFlo, or IRTrue), which determines the light spectrum used for image capture.</p> <p>The IRLightSurgN is connected to the SmartSurgN Laparoscope using a fiber optic light cable. Additionally, the SmartSurgN OptIcRSurgN 10mm ICG Laparoscope connects to the PrizMCurgN Camera Head.</p> <p>Images are acquired by the PrizMCurgN Camera Head and transmitted to the EyeRSurgN Console. Images are processed by the EyeRSurgN Console and outputted to the View4SurgN 4K medical grade monitor. If connecting a Rec4KSurgN 4K video recorder to the EyeRSurgN Console, a record of the surgical procedure can be saved.</p>
Predicate Device:	<p>SmartSurgN Visualization System (K213943)</p> <p>Regulation: 876.1500 Product Code: OWN</p>

Technological Comparison

The SmartSurgN Visualization System was previously cleared under K213943 and is the primary predicate device; the predicate device has not been subject to any design-related recalls. The subject device has the same intended use, indications for use, intended users, and use environment as the predicate device.

Item/Feature	Proposed Device K242163	Predicate Device K213943
	SmartSurgN Visualization System	SmartSurgN Visualization System
Intended Use	The SmartSurgN Visualization System is intended to provide real-time endoscopic visible (VIS) and real-time near-infrared (NIR) fluorescence imaging during minimally invasive surgery.	Same as proposed device
Indications for Use	The SmartSurgN Visualization System is intended to provide real-time endoscopic visible (VIS) and real-time near-infrared (NIR) fluorescence	Same as proposed device

Item/Feature	Proposed Device K242163	Predicate Device K213943
	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 Design	4K, 4CMOS video signal processing and projection with LED illumination and NIR laser excitation	Same as proposed device
Component Device:	IRLightSurgN Light Source and EyeRSurgN	
Packaging: Physical Dimensions	EyeRSurgN, IRLightSurgN = 12"x12"x4.5" (30cm x30cmx11cm)	Same as proposed device
Packaging: Weight	EyeRSurgN = 9 lb. (4kg) IRLightSurgN = 10 lb. (4.5kg)	Same as proposed device
Device Design	4K, 4CMOS video signal processing and projection with LED illumination and NIR laser excitation	Same as proposed device
Component Device:	PrizMCurgN	
Reprocessing: Cleaning	Manual	Same as proposed device
Device Design	4K, 4CMOS video signal processing and projection with LED illumination and NIR laser excitation	Same as proposed device
Reprocessing: Sterilization Methods	Ethylene Oxide	Same as proposed device
Component Device:	OptIcRSurgN Laparoscope	
Outer diameter	10mm	Same as proposed device
Working Length	31 cm	Same as proposed device
DOV	0°, 30°	Same as proposed device
FOV	70°	Same as proposed device
Patient-Contacting Materials	Stainless Steel, Epoxy, Sapphire, PEEK	Same as proposed device
Single or Reusable	Reusable	Same as proposed device
Cleaning	Manual	Same as proposed device
Sterilization Methods	Steam Sterilization	Same as proposed device
Sterility Assurance Level	10 ⁻⁶	Same as proposed device

The SmartSurgN Visualization System was previously cleared under K213943 and is the primary predicate device for this submission. The predicate device has not been subject to any design-related

recalls. The SmartSurgN Visualization System provides real-time endoscopic visible (VIS) and near-infrared (NIR) fluorescence imaging to support minimally invasive surgical procedures. The subject SmartSurgN Visualization System has the same intended use, indications for use, intended users, and use environment as the predicate device. It continues to enable surgeons to perform minimally invasive surgery using standard endoscopic visible light and NIR fluorescence imaging when used with indocyanine green (ICG), consistent with the cleared indications. No new clinical claims or standalone use claims are introduced.

There are no design changes to the imaging console, camera head, surgical light source, or system operation compared to the predicate device. The major technological characteristics, including image acquisition, optical signal transmission, image processing, illumination, and display output, remain unchanged. Updates to software that improve device reliability and operator usability were tested and released.

The subject device includes the addition of laparoscope suppliers. The laparoscope maintains the same diameter, working length range, field of view, materials, and patient-contacting profile as the predicate laparoscope.

Performance Testing

Non-Clinical Testing:

The following non-clinical testing was performed to support the safety and substantial equivalence.

Item/Feature	Verification/Validation Method(s)	Acceptance Criteria	Summary of Results
Electrical Safety and EMC	in accordance with IEC60601-1-1:2005 +AMD1:2012 CSV Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Meet IEC60601-1-1:2005+AMD1:2012 CSV	Pass
	in accordance with IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	Meet IEC 60601-1-2:2014	Pass
	in accordance with EN IEC60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements	Meet EN IEC60825-1:2014	Pass
ISO 8600-5 Second Edition 2020-10	in accordance with ISO 8600-5 Second Edition 2020-10, Optics and photonics - Medical endoscopes and endotherapy devices - Part 5: Determination of optical resolution of rigid endoscopes with optics	Meet ISO 8600-5 Second Edition 2020-10	Pass
	In accordance with ISO 8600-3 Second Edition 2019-8 Endoscopes - Medical endoscopes and endotherapy devices Part 3: Determination of field of view and direction of view of endoscopes with optics.	Meet ISO 8600-3 Second Edition 2019-8	Pass
Software	In accordance with IEC62304:2006 Medical device software - Software life cycle processes	Meet IEC62304:2006	Pass
	ISO/IEC 27000:2016 Information Technology - Security techniques - Information security	ISO/IEC 27000:2016	Pass

	management systems - Overview and vocabulary			
Packaging	in accordance with ISTA 2A-2011 Packaged-Products Weighing 150 Lb (68 Kg) Or Less	Meet ISTA 2A-2011	Pass	
Device Change	Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of Results
Additional laparoscope suppliers added as a device component alternate source	Patient Infection	Performance Specifications and Testing: ICG Fluorescence Sensitivity Test	Substantially equivalent to Predicate Device	Pass
	Device failure causes patient injury or delay in procedure.	Performance Specifications and Testing: Brightness Uniformity and Illumination Test	Substantially equivalent to predicate device	Pass
		Performance Specifications and Testing	ISO 8600-1:2015-10-15, ISO 8600-3:2019-08, ISO 8600-5:2020	Pass
		Performance Specifications and Testing: Image Quality Comparison	Substantially equivalent to predicate device	Pass
		Sterilization validation was conducted using FDA-recognized methods to demonstrate sterility assurance.	Devices shall maintain package integrity and have SAL of 10 ⁻⁶ .	Sterilization validation testing results passed (n=3). Sterilization validation established SAL of 10 ⁻⁶ .
Rec4KSurgN 4K video recorder added as an accessory	Malfunction during procedure Device failure causes delay in procedure	Compatibility testing was completed using TP-32 Test Protocol for TEAC Video Recording Accessory Compatibility	Device shall record video image without error.	Compatibility Verification testing results passed (n=1).

Note: No clinical investigations were required for a determination of substantial equivalence.

Conclusion

The SmartSurgN Visualization System has the same intended use, indications for use, technological characteristics, and principles of operation as the predicate device cleared under K213943. Non-clinical testing demonstrates that the subject device is as safe, as effective, and performs as well as or better than the predicate device.