June 14, 2022

Richard Wolf Medical Instruments Corporation
Michael Loiterman
US Head of Regulatory - QA/QC
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061

Re: K212808
Trade/Device Name: Logic Hd camera head green, System green
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FET, GCJ
Dated: September 2, 2021
Received: September 3, 2021

Dear Michael Loiterman:

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,

For Purva Pandya
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)*
K212808

Device Name
System Green

Indications for Use *(Describe)*
Upon intravenous administration of TRADENAME (ICG drug product), System green is used with TRADENAME (ICG drug product) to perform intraoperative fluorescence angiography, and it is also indicated for use in fluorescence imaging of biliary ducts, and when indicated, during intraoperative cholangiography.

System green is indicated for use to provide real time endoscopic visible and near-infrared fluorescence imaging. System green enables 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 or common hepatic duct), using near-infrared imaging.
Fluorescence imaging of biliary ducts with System green 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.

Upon interstitial administration of TRADENAME (ICG drug product), System green is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K212808

Device Name
Light Source LED Green

Indications for Use *(Describe)*
ICG light sources
The products are used for providing white light and near-infrared light for diagnostic and therapeutic application, specifically in endoscopy.
The Light source LED green ENDOLIGHT can be used to provide real time endoscopic imaging using standard endoscope visible light and near-infrared fluorescence imaging, this enables surgeons to perform:
• Minimally invasive surgery.
• Visual assessments of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near-infrared imaging.
• Intraoperative cholangiography.

Upon intravenous administration of TRADENAME (ICG drug product), ICG light sources can be used with System green to perform:
• Intraoperative fluorescence angiography.
• Fluorescence imaging of biliary ducts, and when indicated during intraoperative cholangiography.

Upon interstitial administration of TRADENAME (ICG drug product), ICG light sources can be used with System green to perform:

• Intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

The Light source LED green ENDOLIGHT 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)

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K212808

Device Name
Fiber Light Cable

Indications for Use *(Describe)*
Light cable
The products are used to transmit light in the visible spectral range from the light source to the application-specific instrument set.
Fiber Light Cables are used to provide real time endoscopic imaging using standard endoscopic visible light and near-infrared fluorescence imaging, this enables surgeons to perform:
• Minimally invasive surgery.
• Visual assessments of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near-infrared imaging.
• Intraoperative cholangiography.

Upon intravenous administration of TRADENAME (ICG drug product), fiber light cables can be used with System green to perform:
• Intraoperative fluorescence angiography.
• Fluorescence imaging of biliary ducts, and when indicated during intraoperative cholangiography.

Upon interstitial administration of TRADENAME (ICG drug product), fiber light cables can be used with System green to perform:
• Intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Light cables are not intended for standalone use for biliary duct visualization.

Adapter for light cable
The products are used to connect light guides to light sources or endoscopes.

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K212808

Device Name
Logic HD Camera Controller and Logic 4K Camera Controller

Indications for Use *(Describe)*
Camera Controller
The Logic HD Camera Controller 552510x and the Logic 4K Camera Controller 5525301 have been designed for high-definition video endoscopy and can be used for both diagnostic and therapeutic interventions.
The Camera Controllers are used in conjunction with other video equipment and endoscopic accessories.
The Logic HD Camera Controller and the Logic 4K Camera Controller can be used to provide real time endoscopic imaging using standard endoscope visible light and near-infrared fluorescence imaging, this enables surgeons to perform:
• Minimally invasive surgery.
• Visual assessments of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near-infrared imaging.
• Intraoperative cholangiography.

Upon intravenous administration of TRADENAME (ICG drug product), Camera Controllers can be used with System green to perform:
• Intraoperative fluorescence angiography.
• Fluorescence imaging of biliary ducts, and when indicated during intraoperative cholangiography.

Upon interstitial administration of TRADENAME (ICG drug product), Camera Controllers can be used with System green to perform:
• Intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Camera Controllers are 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)

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Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K212808

Device Name
Logic HD Camera Head Green

Indications for Use *(Describe)*
The Logic HD camera head green is used to provide real time endoscopic imaging using standard endoscope visible light and near-infrared fluorescence imaging, this enables surgeons to perform:
• Minimally invasive surgery.
• Visual assessments of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near-infrared imaging.
• Intraoperative cholangiography.

Upon intravenous administration of TRADENAME (ICG drug product), Logic HD camera head green can be used with System green to perform:
• Intraoperative fluorescence angiography.
• Fluorescence imaging of biliary ducts, and when indicated during intraoperative cholangiography.

Upon interstitial administration of TRADENAME (ICG drug product), Logic HD camera head green can be used with System green to perform:
• Intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

The Logic HD camera head green 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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212808

Device Name
PANOVIEW ULTRA Telescopes 10 mm

Indications for Use *(Describe)*
PANOVIEW ULTRA Telescopes are used to provide real time endoscopic imaging using standard endoscopic visible light and near-infrared fluorescence imaging, this enables surgeons to perform:
• Minimally invasive surgery.
• Visual assessments of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near-infrared imaging.
• Intraoperative cholangiography.

Upon intravenous administration of TRADENAME (ICG drug product), PANOVIEW ULTRA Telescopes can be used with System green to perform:
• Intraoperative fluorescence angiography.
• Fluorescence imaging of biliary ducts, and when indicated during intraoperative cholangiography.

Upon interstitial administration of TRADENAME (ICG drug product), PANOVIEW ULTRA Telescopes can be used with System green to perform:

• Intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

PANOVIEW ULTRA Telescopes are 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)

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5 510(k) Summary

I Submitter

Richard Wolf Medical Instruments Corporation
353 Corporate Woods Parkway
Vernon Hills, IL 60046

Phone: (847) 913 1113
Fax: (847) 913 0924

Contact Person, Title: Mr. Stefan D Heffner
Date Prepared: March 15, 2022

Legal Manufacturer

Richard Wolf GmbH
Pforzheimer Straße 32
75438 Knittlingen

II Device

Table 5 .1: Devices for which clearance is requested.

Brand name	Trade name	Model No.	Device classification name	Regulation Number and Name	Product Code	Device Class	Review Panel
ENDOCAM	*System green*	*System green*	N/A	N/A	N/A	N/A	N/A
ENDOLIGHT	Light Source LED Green Foot Control Rockerswitch	5165002 2030.105	Led light source Laparoscope, General & Plastic Surgery System, X-ray, Angiographic	876.1500 876.1500 892.1600	NTN GCJ IZI	II	Gastro-enterology / Urology General & Plastic Surgery Radiology

Brand name	Trade name			Model No.	Device classification name	Regulation Number and Name	Product Code	Device Class	Review Panel
FUSION	Fiber Light Cable Ø5mm TL 2.3M	Fiber Light Cable Ø5mm TL 2.3M	Fiber Light Cable Ø5mm TL 2.3M	806550xx	Accessories, photographic, for endoscope (exclude light sources) Laparoscope, General & Plastic Surgery System, X-ray, Angiographic	876.1500 876.1500 892.1600	FEM GCJ IZI	I II II	Gastro-enterology / Urology General & Plastic Surgery Radiology

Brand name	Trade name	Model No.	Device classification name	Regulation Number and Name	Product Code	Device Class	Review Panel
ENDOCAM	Logic HD Camera Controller	552510x	Endoscope Video Imaging System/ Component Laparoscope, General & Plastic Surgery System, X-ray, Angiographic	876.1500 876.1500 892.1600	FET GCJ IZI	II	Gastro-enterology / Urology General & Plastic Surgery Radiology
ENDOCAM	Logic 4K Camera Controller	5525301	Endoscope Video Imaging System/ Component Laparoscope, General & Plastic Surgery System, X-ray, Angiographic	876.1500 876.1500 892.1600	FET GCJ IZI	II	Gastro-enterology / Urology General & Plastic Surgery Radiology

Brand name	Trade name	Model No.	Device classification name	Regulation Number and Name	Product Code	Device Class	Review Panel
ENDOCAM	Logic HD camera head green	85525812	Endoscope Video Imaging System/ Component Laparoscope, General & Plastic Surgery System, X-ray, Angiographic	876.1500 876.1500 892.1600	FET GCJ IZI	II	Gastro-enterology / Urology General & Plastic Surgery Radiology

Brand name	Trade name	Model No.	Device classification name	Regulation Number and Name	Product Code	Device Class	Review Panel
PANOVIEW Ultra telescopes	TELESCOPE 0° Ø 10MM WL 305MM TELESCOPE 30° Ø 10MM WL 305MM TELESCOPE 50° Ø 10MM WL 305MM TELESCOPE 0° Ø 10MM WL 440MM TELESCOPE 30° Ø 10MM WL 440MM TELESCOPE 50° Ø 10MM WL 440MM	893446x 893444x6	Rigid Endoscope Laparoscope, General & Plastic Surgery Laparo-scope Gyneco-logic System, X-ray, Angiographic	876.1500 876.1500 876.1500 892.1600	GCM GCJ HET IZI	II	Gastro-enterology / Urology General & Plastic Surgery General & Plastic Surgery Radiology

III Predicate Device

Table 1: List of predicate devices

Name of Predicate Device: PINPOINT Endoscopic Fluorescence Imaging System (PC9000) 510(k) Number: K182606 Regulatory Class: II Product Code: GCJ, IZI Manufacturer: Novadaq Technologies ULC (now a part of Stryker) The predicate has been subject to a design related recall (Recall Event ID 87540). This recall has no influence on the current submission as the product that was subject of the recall was the imaging processor which is not part of the comparison within this submission.
Name of Predicate Device: Light Source LED 2.1 80W 510(k) Number : 510k exempt Regulatory Class: II Product Code: NTN Manufacturer: Richard Wolf GmbH The predicate has not been subject to a design related recall
Name of Predicate Device: FIBER LIGHT CABLE Ø 5MM TL 2.3M / 3M / 3.5M 510(k) Number : 510k exempt Regulatory Class: I Product Code: FEM Manufacturer: Richard Wolf GmbH The predicate has not been subject to a design related recall.
Name of Predicate Device: Logic HD Camera Controller 510(k) Number : K200617 Regulatory Class: II Product Code: FET Manufacturer: Richard Wolf GmbH The predicate has not been subject to a design related recall.
Name of Predicate Device: Logic 4K Camera Controller 510(k) Number : K200617 Regulatory Class: II Product Code: FET Manufacturer: Richard Wolf GmbH The predicate has not been subject to a design related recall.
Name of Predicate Device: Logic 4K Camera Head 510(k) Number : K180583 Regulatory Class: II Product Code: FET Manufacturer: Richard Wolf GmbH The predicate has not been subject to a design related recall.
Name of Predicate Device: Panoview Ultra telescopes 10mm 510(k) Number : K203226 Regulatory Class: II Product Code: GCM / GCJ /HET Manufacturer: Richard Wolf GmbH The predicate has not been subject to a design related recall.

Reference Devices

Table 2: List of reference devices

Name of Reference Device: Fiber Light Cable Ø4.5MM TL 3.6M 510(k) Number : 510k exempt Regulatory Class: I Product Code: FEM Manufacturer: Richard Wolf GmbH

5.1 Subject Device Description - *System green*

5.1.1 Device Identification

Table 5.2: Subject device

Brand name	Trade name	Type number
ENDOCAM	*System green*	*System green*

5.1.2 Device characteristics

Software

System green includes component devices with software.

Materials with patient contact

Component devices of *System green* have direct or indirect tissue/patient contact.

Single use / reusable

All parts of *System green* are reusable.

Delivered sterile / non-sterile

All parts of *System green* are provided non-sterile to the user.

5.1.3 Environment of Use

System green is designed for use in a healthcare facility or hospital.

5.1.4 Brief written description of the device

System green combines the camera head, the rigid endoscope, the light source including light cables and a foot switch and the camera controller. The camera head is connected via a standard camera cable while the connection between the camera controller and light source is possible via a LAN (Ethernet) connection cable. This is the precondition for the video in fluorescence mode.

The camera head is further connected to the rigid endoscope via a snap-on locking mechanism. The rigid endoscope is further coupled via the fiber light cable to the light source, which can also be connected to an optional foot switch.

System green allows for fluorescence imaging by exciting indocyanine green (ICG), a dye (FDA approved drug, not included in this submission) that is applied intravenously or interstitially in the body. Fluorescence imaging and white light imaging is possible with the same system setup at the same time. The NIR images can only be displayed as overlay pictures with the NIR information added to the white light image. The white light image can also be displayed on its own.

5.1.5 Materials of Use

The materials of *System green* are listed in the corresponding submissions of each main part.

5.1.6 Key Performance Characteristics

The Key Performance characteristic of *System green* is the visualization with standard of care visible light and near infrared imaging.

5.2 Subject Device Description - Light Source LED Green

5.2.1 Device Identification

Table 5.3: Subject device

Brand name	Trade name	Type number
ENDOLIGHT	Light Source LED Green and Foot Control Rockerswitch	5165002 2030.105

5.2.2 Device characteristics

Software

Light Source LED Green includes Software.

Materials with patient contact

Light Source LED Green does not have any direct or indirect tissue/patient contact.

Single use / reusable

Light Source LED Green is reusable.

Delivered sterile / non-sterile

Light Source LED Green is provided non-sterile to the user.

5.2.3 Environment of Use

Light Source LED Green is designed for use in a healthcare facility or hospital.

5.2.4 Brief written description of the device

The light source is used for diagnostic and therapeutic endoscopic procedures. The use of LED illuminants generates light that is transported from the light source to the endoscope by a light guide cable, thus enabling adequate illumination of the surgical field.

It is used in combination with a camera control unit as well as a suitable camera head, a fiber optic cable, and an endoscope specifically for near-infrared (NIR) endoscopy.

5.2.5 Materials of Use

Metal housing

5.2.6 Key Performance Characteristics

The Key Performance characteristic of Light Source LED Green is providing white light and near-infrared light.

5.3 Subject Device Description - Fiber Light Cable

5.3.1 Device Identification

Table 5.4: Subject device

Brand name	Trade name	Type number
FUSION	Fiber Light Cable Ø5mm TL 2.3M	80655023
	Fiber Light Cable Ø5mm TL 3M	80655030
	Fiber Light Cable Ø5mm TL 3.5M	80655035

5.3.2 Device characteristics

Software

Fiber Light Cable does not include Software.

Materials with patient contact

Fiber Light Cable does not have any direct or indirect tissue/patient contact.

Single use / reusable

Fiber Light Cable is reusable.

Delivered sterile / non-sterile

Fiber Light Cable is provided non-sterile to the user.

5.3.3 Environment of Use

Fiber Light Cable is designed for use in a healthcare facility or hospital.

5.3.4 Brief written description of the device

The products are used to transmit light from the light source to the application-specific instrument set.

5.3.5 Materials of Use

Optical glass, Plastic, Silicone, Stainless Steel.

5.3.6 Key Performance Characteristics

The Key Performance characteristic of Light Source LED Green is transmitting light.

5.4 Subject Device Description - Logic HD Camera Controller

5.4.1 Device Identification

Table 5.5: Subject device

Brand name	Trade name	Type number
ENDOCAM	Logic HD Camera Controller	5525101
		5525102
		5525103
		5525104
		5525105
		5525106
		5525107
		5525108

5.4.2 Device characteristics

Software

Logic HD Camera Controller includes Software

Materials with patient contact

Logic HD Camera Controller does not have any direct or indirect tissue/patient contact.

Single use / reusable

Logic HD Camera Controller is reusable.

Delivered sterile / non-sterile

Logic HD Camera Controller is provided non-sterile to the user.

5.4.3 Environment of Use

Logic HD Camera Controller is designed for use in a healthcare facility or hospital.

5.4.4 Brief written description of the device

The products are used for displaying the image of natural or artificial hollow spaces obtained by an endoscope within the scope of diagnostic or therapeutic endoscopy.

5.4.5 Materials of Use

Metal housing

5.4.6 Key Performance Characteristics

The Key Performance characteristics of Logic HD Camera Controller are image recording and signal processing of the image data.

5.5 Subject Device Description - Logic 4K Camera Controller

5.5.1 Device Identification

Table 5.6: Subject device

Brand name	Trade name	Type number
ENDOCAM	Logic 4K Camera Controller	5525301

5.5.2 Device characteristics

Software

Logic 4K Camera Controller includes Software

Materials with patient contact

Logic 4K Camera Controller does not have any direct or indirect tissue/patient contact.

Single use / reusable

Logic 4K Camera Controller is reusable.

Delivered sterile / non-sterile

Logic 4K Camera Controller is provided non-sterile to the user.

5.5.3 Environment of Use

Logic 4K Camera Controller is designed for use in a healthcare facility or hospital.

5.5.4 Brief written description of the device

The products are used for displaying the image of natural or artificial hollow spaces obtained by an endoscope within the scope of diagnostic or therapeutic endoscopy.

5.5.5 Materials of Use

Metal housing

5.5.6 Key Performance Characteristics

The Key Performance characteristics of Logic 4K Camera Controller are image recording and signal processing of the image data.

5.6 Subject Device Description - Logic HD camera head green

5.6.1 Device Identification

Table 5.7: Subject device

Brand name	Trade name	Type number
ENDOCAM	Logic HD camera head green	85525812

The Logic HD camera head green has been designed to convert the image of the inside of the body, generated by an endoscope, into an electrical signal which is passed on to a camera controller, and to optically filter the excitation light within the scope of the ICG fluorescence imaging diagnostic procedure.

5.6.2 Device characteristics

Software

The Logic HD camera head green does not include software.

Materials with patient contact

The Logic HD camera head green does not have any direct or indirect tissue/patient contact.

Single use / reusable

The Logic HD camera head green is reusable.

Delivered sterile / non-sterile

Logic HD camera head green provided non-sterile to the user.

5.6.3 Environment of Use

The Logic HD camera head green is designed for use in a healthcare facility or hospital.

5.6.4 Brief written description of the device

The camera head serves as a link between the endoscope and the camera controller. The image generated by the attached endoscope is passed on via the camera head to the corresponding camera controller where it is processed.
The Logic HD camera head green is used for diagnostic and therapeutic interventions with white light and near infrared light. When operated in combination with further products of the "green" model line, the Logic HD camera head green can be used for visualizing the fluorescence of a dye in the near infrared (NIR) range (indocyanine (ICG)).

5.6.5 Materials of Use

Plastic, Silicone, Stainless Steel, Metal, Optical glass.

5.6.6 Key Performance Characteristics

The Key Performance characteristic of the camera head is detecting the light at a certain wavelength and converting this information into electrical signals for further processing.

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5.7 Subject Device Description Panoview Ultra telescopes

5.7.1 Device Identification

Table 5.8: Subject device

Brand name	Trade name	Type number
PANOVIEW Ultra telescopes	TELESCOPE 0° Ø 10MM WL 305MM	8934461
	TELESCOPE 30° Ø 10MM WL 305MM	8934462
	TELESCOPE 50° Ø 10MM WL 305MM	8934463
	TELESCOPE 0° Ø 10MM WL 440MM	89344416
	TELESCOPE 30° Ø 10MM WL 440MM	89344426
	TELESCOPE 50° Ø 10MM WL 440MM	89344436

5.7.2 Device characteristics

Software

PANOVIEW Ultra telescopes do not include Software

Materials with patient contact

PANOVIEW Ultra telescopes do have direct or indirect tissue/patient contact.

Single use / reusable

PANOVIEW Ultra telescopes are reusable.

Delivered sterile / non-sterile

PANOVIEW Ultra telescopes are provided non-sterile to the user.

5.7.3 Environment of Use

PANOVIEW Ultra telescopes are designed for use in a healthcare facility or hospital.

5.7.4 Brief written description of the device

The 10 mm PANOVIEW Ultra Telescopes are rigid endoscopes with fixed eyepiece, integrated light guide, optical system, cold light connector, with screw-on adapter for fiber light cables and with color coding ring for direction of view.

5.7.5 Materials of Use

Optical glass, Stainless steel

5.7.6 Key Performance Characteristics

The Key Performance characteristic of the PANOVIEW Ultra telescopes is to provide real time endoscopic images.

5.8 Indications for Use

5.8.1 *System Green*

Upon intravenous administration of TRADENAME (ICG drug product), System green is used with TRADENAME (ICG drug product) to perform intraoperative fluorescence angiography, and it is also indicated for use in fluorescence imaging of biliary ducts, and when indicated, during intraoperative cholangiography.

System green is indicated for use to provide real time endoscopic visible and near-infrared fluorescence imaging. System green enables 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 or common hepatic duct), using near-infrared imaging.

Fluorescence imaging of biliary ducts with System green 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.

Upon interstitial administration of TRADENAME (ICG drug product), System green is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes

5.8.2 Light Source LED Green

ICG light sources

The products are used for providing white light and near-infrared light for diagnostic and therapeutic application, specifically in endoscopy.
The Light source LED green ENDOLIGHT can be used to provide real time endoscopic imaging using standard endoscope visible light and near-infrared fluorescence imaging, this enables surgeons to perform:

- Minimally invasive surgery.
- Visual assessments of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near-infrared imaging.
- Intraoperative cholangiography.

Upon intravenous administration of TRADENAME (ICG drug product), ICG light sources can be used with System green to perform:

- Intraoperative fluorescence angiography.
- Fluorescence imaging of biliary ducts, and when indicated during intraoperative cholangiography.

Upon interstitial administration of TRADENAME (ICG drug product), ICG light sources can be used with System green to perform:

- Intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

The Light source LED green ENDOLIGHT is not intended for standalone use for biliary duct visualization.

5.8.3 Fiber Light Cables

Light cable

The products are used to transmit light in the visible spectral range from the light source to the application-specific instrument set.

Fiber Light Cables are used to provide real time endoscopic imaging using standard endoscopic visible light and near-infrared fluorescence imaging, this enables surgeons to perform:

- Minimally invasive surgery.
- Visual assessments of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near-infrared imaging.
- Intraoperative cholangiography.

Upon intravenous administration of TRADENAME (ICG drug product), fiber light cables can be used with System green to perform:

- Intraoperative fluorescence angiography.
- Fluorescence imaging of biliary ducts, and when indicated during intraoperative cholangiography.

Upon interstitial administration of TRADENAME (ICG drug product), fiber light cables can be used with System green to perform:

- Intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Light cables are not intended for standalone use for biliary duct visualization.

Adapter for light cable

The products are used to connect light guides to light sources or endoscopes.

5.8.4 Logic HD Camera Controller and Logic 4K Camera Controller

Camera Controller

The Logic HD Camera Controller 552510x and the Logic 4K Camera Controller 5525301 have been designed for high-definition video endoscopy and can be used for both diagnostic and therapeutic interventions.
The Camera Controllers are used in conjunction with other video equipment and endoscopic accessories.
The Logic HD Camera Controller and the Logic 4K Camera Controller can be used to provide real time endoscopic imaging using standard endoscope visible light and near-infrared fluorescence imaging, this enables surgeons to perform:

- Minimally invasive surgery.
- Visual assessments of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near-infrared imaging.
- Intraoperative cholangiography.

Upon intravenous administration of TRADENAME (ICG drug product), Camera Controllers can be used with System green to perform:

- Intraoperative fluorescence angiography.
- Fluorescence imaging of biliary ducts, and when indicated during intraoperative cholangiography.

Upon interstitial administration of TRADENAME (ICG drug product), Camera Controllers can be used with System green to perform:

- Intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Camera Controllers are not intended for standalone use for biliary duct visualization.

5.8.5 Logic HD camera head green

The Logic HD camera head green is used to provide real time endoscopic imaging using standard endoscope visible light and near-infrared fluorescence imaging, this enables surgeons to perform:

- Minimally invasive surgery.
- Visual assessments of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near-infrared imaging.
- Intraoperative cholangiography.

Upon intravenous administration of TRADENAME (ICG drug product), Logic HD camera head green can be used with System green to perform:

- Intraoperative fluorescence angiography.
- Fluorescence imaging of biliary ducts, and when indicated during intraoperative cholangiography.

Upon interstitial administration of TRADENAME (ICG drug product), Logic HD camera head green can be used with System green to perform:

- Intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

The Logic HD camera head green is not intended for standalone use for biliary duct visualization.

5.8.6 PANOVIEW Ultra telescopes

PANOVIEW ULTRA Telescopes are used to provide real time endoscopic imaging using standard endoscopic visible light and near-infrared fluorescence imaging, this enables surgeons to perform:

- Minimally invasive surgery.
- Visual assessments of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near-infrared imaging.
- Intraoperative cholangiography.

Upon intravenous administration of TRADENAME (ICG drug product), PANOVIEW ULTRA Telescopes can be used with System green to perform:

- Intraoperative fluorescence angiography.
- Fluorescence imaging of biliary ducts, and when indicated during intraoperative cholangiography.

Upon interstitial administration of TRADENAME (ICG drug product), PANOVIEW ULTRA Telescopes can be used with System green to perform:

- Intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

PANOVIEW ULTRA Telescopes are not intended for standalone use for biliary duct visualization.

5.9 Comparison of Technological Characteristics with the Predicate Device

For each component device, two predicate devices were used. The primary predicate device was the PINPOINT device, which was used to cover the new indications for use in the context of *System green.*

As secondary predicate device, a Richard Wolf device was selected to cover any differences in technology between the subject component device and the primary predicate device. Therefore, the comparability of the subject devices with the predicate devices is ensured for all component devices.

5.10 Summary of Performance Testing

5.10.1 Non-clinical Performance Testing

5.10.1.1 Electromagnetic Compatibility and Electrical Safety

Electromagnetic compatibility and electrical safety testing proved compliance with the following standards for the component devices of *System Green*

- IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1:2012 reprint recognition number 19-4): Medical electrical equipment Part 1;

  including national differences according to National Standard AAMI/IEC 60601-1:2005 + AMD 1:2012 United States of America ANSI/AAMI ES60601-1:2005 / A2:2010 corresponding to ANSI/AAMI ES60601-1:2005/(R):2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
- IEC 60601-1-6:2010, AMD1:2013 (recognition number 5-89) for use in conjunction with IEC 62366:2007, AMD1:2014 and IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1: 2012 or equivalent consolidated version IEC 60601-1:2012 (Edition 3.1)
- IEC 60601-1-2:2014 (recognition number 19-8) Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
- IEC 60601-2-18:2009 (Third Edition) (recognition number 9-114) Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

5.10.1.2 Performance Testing

Photobiological safety testing according to IEC 62471 was conducted by an accredited testing laboratory. The product under test was assigned to risk group 2.

NIR power and wavelength spectrum of the Light Source LED Green was measured and verified.

Temperature safety testing at the distal end of the PANOVIEW Ultra telescope was performed and found to be within the specified limits according to IEC 60601-2-18.

Tightness of the Logic HD camera head green with a minimum protection degree of IPX7 according to IEC 60529 was ensured. The tightness of the camera head was determined to be suitable for steam sterilization.

To demonstrate that functionality is still given after specified storage and transport conditions, transport simulation according to ISO 11607-1 and ASTM D4169 was performed. Functional testing before and after transport confirmed that the packaging is suitable and is not subject to safety or performance concerns.

5.10.2 Animal Testing

Animal testing was performed to evaluate the effectiveness and performance of *System green* in a pre-clinical model as well as to evaluate the risk of incorrect fluorescence using the subject device. The test results show that the subject device met all specified acceptance criteria set out for the animal testing, and that the performance of the device with respect to the risk of incorrect fluorescence has been confirmed.

Animal testing verified the effectiveness as described in the indications for use.

5.11 Conclusion

System green and its component device has similar indications for use as the predicate device PINPOINT and the predicate devices from Richard Wolf.

The nonclinical tests demonstrate that the devices are as safe and as effective as the legally marketed device.

Therefore, *System green* and the component devices were deemed substantially equivalent to the legally marketed devices.