February 23, 2023

Schoelly Fiberoptic GmbH
% Pamela Papineau
Regulatory Affairs Consultant (Alternate Application Contact)
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K221591
Trade/Device Name: Camera System (Camera Control Unit, Camera Head to be coupled to a fiberoptic scope), NIR FI Light Source
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, FET, OWN, FCW
Dated: January 24, 2023
Received: January 27, 2023

Dear Pamela Papineau:

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)*
K221591

Device Name
Near-Infrared (NIR) Fluorescence Imaging (FI) System: Camera System (Camera Control Unit, Camera Head to be coupled to a fiberoptic scope); NIR FI Light Source

Indications for Use *(Describe)*

Camera System:

The Camera System is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery whenever a laparoscope/ endoscope/ arthroscope is indicated for use. A few examples of the more common endoscope surgeries are Laparoscopic cholecystectomy, Laparoscopic hernia repair, Laparoscopic appendectomy, Laparoscopic pelvic lymph node detection, Laparoscopically assisted hysterectomy, Laparoscopic and thorascopic anterior spinal fusion, Anterior cruciate ligament reconstruction, Knee arthroscopy, Small joint arthroscopy, Decompression fixation, Wedge resection, Lung biopsy, Pleural biopsy, Dorsal sympathectomy, Pleurodesis, Internal mammary artery dissection for coronary artery bypass, Coronary artery bypass grafting where endoscopic visualization is indicated and Examination of the evacuated cardiac chamber during performance of valve replacement. The users of the Camera System are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

NIR FI Light Source:

The NIR FI Light Source and NIR FI Light Guide are indicated for use to provide real-time endoscopic visible and near-infrared fluorescence imaging. The NIR FI Light Source and NIR FI Light Guide enable surgeons to perform minimally invasive surgery using standard endoscope visual 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 NIR FI Light Source and NIR FI Light Guide is 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.

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.

005_510(k) Summary - K221591

A. GENERAL INFORMATION

510(k) Sponsor: Schoelly Fiberoptic GmbH
Address: Robert-Bosch-Str. 1 – 3
79211 Denzlingen
Germany
FDA Registration Number: 8043903
Telephone Number: +49-7666-980-0
Fax Number: +49-7666-908-380
Contact Person: Dr. Sandra Baumann
Date Prepared: 23 May 2022

B. DEVICE IDENTIFICATION

The subject device is the SCHOELLY Near-Infrared (NIR) Fluorescence Imaging (FI) System that is specifically comprised of the flowing components:

Trade Name	Camera System (Camera Control Unit, Camera Head to be coupled to a fiberoptic scope)
Common Name	Video Camera (Camera Control Unit, Camera Head to be coupled to a fiberoptic scope)
Classification Name	Laparoscope, General & Plastic Surgery Endoscopic Video Imaging System/Component, Gastroenterology-Urology
Product Code	GCJ FET
Regulation Number	21 CFR 876.1500
Regulation Name	Endoscope and accessories
Device Classification	Class II
Regulation Medical Specialty	Gastroenterology/Urology
Review Panels	General & Plastic Surgery Gastroenterology/Urology

Trade Name	NIR FI Light Source
Common Name	Light Source, Illuminator
Classification Name	Confocal Optical Imaging[1]

	Light Source, Fiberoptic, Routine[2]
Product Code	OWN[1] FCW[2]
Regulation Number	21 CFR 876.1500
Regulation Name	Endoscope and accessories
Device Classification	Class II
Regulation Medical Specialty	Gastroenterology/Urology
Review Panels	General & Plastic Surgery[1] Gastroenterology/Urology[2]

[1] when used for 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 NIR Fluorescence Imaging
[2] when used to emit light in the visible range of the spectrum to support standard endoscopic imaging

Indications for Use

Camera System

The Camera System is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery whenever a laparoscope/ endoscope/ arthroscope is indicated for use. A few examples of the more common endoscope surgeries are Laparoscopic cholecystectomy, Laparoscopic hernia repair, Laparoscopic appendectomy, Laparoscopic pelvic lymph node detection, Laparoscopically assisted hysterectomy, Laparoscopic and thorascopic anterior spinal fusion, Anterior cruciate ligament reconstruction, Knee arthroscopy, Small joint arthroscopy, Decompression fixation, Wedge resection, Lung biopsy, Pleural biopsy, Dorsal sympathectomy, Pleurodesis, Internal mammary artery dissection for coronary artery bypass, Coronary artery bypass grafting where endoscopic visualization is indicated and Examination of the evacuated cardiac chamber during performance of valve replacement. The users of the Camera System are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

NIR FI Light Source

The NIR FI Light Source and NIR FI Light Guide are indicated for use to provide real-time endoscopic visible and near-infrared fluorescence imaging. The NIR FI Light Source and NIR FI Light Guide enable surgeons to perform minimally invasive surgery using standard endoscope visual 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 NIR FI Light Source and NIR FI Light Guide is 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.

C. PREDICATE DEVICE

The predicate device is the STRYKER AIM (Advanced Imaging Modality) System:

510(k) Sponsor: Stryker Endoscopy
510(k) Number: K182160

The predicate device is specifically comprised of the flowing components:

Trade Name	1688 4k Camera System (1688 Camera Control Unit; 1688 AIM 4K Camera Head, C-Mount; 1688 AIM 4K Camera Head with Integrated Coupler; AIM 4K Coupler, 20mm, C-Mount)
Common Name	3-Chip Video Camera (Camera Control Unit, Camera Head and accessories to be coupled to a fiberoptic scope)
Classification Name	Laparoscope, General & Plastic Surgery
Product Code	GCJ
Regulation Number	21 CFR 876.1500
Regulation Name	Endoscope and accessories
Device Classification	Class II
Regulation Medical Specialty	Gastroenterology/Urology
Review Panels	General & Plastic Surgery

Trade Name	L11 LED Light Source with Advanced Imaging Modality
Common Name	Light Source, Illuminator
Classification Name	Confocal Optical Imaging[1] Light Source, Fiberoptic, Routine[2] Fiberoptic light ureteral catheter[3]
Product Code	OWN[1] FCW[2] FCS[3]
Regulation Number	21 CFR 876.1500[1] 21 CFR 876.4020[2, 3]
Regulation Name	Endoscope and accessories

Device Classification	Class II
Regulation Medical Specialty	Gastroenterology/Urology
Review Panels	General & Plastic Surgery[1] Gastroenterology/Urology[2, 3]

Indications for Use

1688 4K Camera System with Advance Imaging Modality

The 1688 Video Camera is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery whenever a laparoscope/ endoscope/ arthroscope is indicated for use. A few examples of the more common endoscope surgeries are Laparoscopic cholecystectomy, Laparoscopic hernia repair, Laparoscopic appendectomy, Laparoscopic pelvic lymph node detection, Laparoscopically assisted hysterectomy, Laparoscopic and thorascopic anterior spinal fusion, Anterior cruciate ligament reconstruction, Knee arthroscopy, Small joint arthroscopy, Decompression fixation, Wedge resection, Lung biopsy, Pleural biopsy, Dorsal sympathectomy, Pleurodesis, Internal mammary artery dissection for coronary artery bypass, Coronary artery bypass grafting where endoscopic visualization is indicated and Examination of the evacuated cardiac chamber during performance of valve replacement. The users of the 1688 Video Camera are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

L11 LED Light Source with Advanced Imaging Modality

The L11 AIM Light Source and SafeLight™ Cable are indicated for use to provide real-time endoscopic visible and near-infrared fluorescence imaging. The L11 AIM Light Source and SafeLight Cable enable surgeons to perform minimally invasive surgery using standard endoscope visual 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 L11 AIM Light Source and SafeLight Cable is 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 L11 AIM Light Source is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.

D. REFERENCE DEVICE

SCHOELLY's TipVision™ Videoscope System serves as a reference device in this submission:

510(k) Sponsor: Schoelly Fiberoptic GmbH
510(k) Number: K201617

The reference device is specifically comprised of the flowing components:

Trade Name	EleVision™ HD 2 Camera Control Unit
Common Name	Camera Control Unit
Classification Names	Endoscopic Video Imaging System/Component
Product Codes	FET
Regulation Numbers	21 CFR 876.1500
Regulation Name	Endoscope and accessories
Device Classification	Class II
Regulation Medical Specialty	Gastroenterology/Urology
Review Panels	Gastroenterology/Urology

Trade Name	TipVision™ Videoscope
Common Name	Video Laparoscope (Camera Head)
Classification Names	Laparoscope, Gynecologic (and Accessories) Laparoscope, General & Plastic Surgery
Product Codes	HET, GCJ
Regulation Numbers	21 CFR 884.1720 21 CFR 876.1500
Regulation Name	Endoscope and accessories
Device Classification	Class II
Regulation Medical Specialty	Obstetrics/Gynecology Gastroenterology/Urology
Review Panels	Obstetrics / Gynecology General & Plastic Surgery

Indications for Use:

The TipVision™ 0°/30° Videoscopes and the other EleVision™ / TipVision™ components are indicated for visualization during general laparoscopy, gynecological laparoscopy, urological laparoscopy, and video-assisted minimally invasive thoracic surgical procedures.

SCHOELLY's Schoelly Laparoscope serves as a further reference device in this submission:

510(k) Sponsor: Schoelly Fiberoptic GmbH
510(k) Number: K143221

Trade Name	Schoelly Laparoscope
Common Name	Laparoscope
Classification Names	Laparoscope, General & Plastic Surgery
Product Codes	GCJ
Regulation Numbers	21 CFR 876.1500
Regulation Name	Endoscope and accessories
Device Classification	Class II
Regulation Medical Specialty	Gastroenterology/Urology
Review Panels	General & Plastic Surgery

Indications for Use:

The Schoelly Laparoscope is indicated for examination of body cavities, hollow organs, and canals, and using additional accessories, to perform various diagnostic and therapeutic procedures.

E. DEVICE DESCRIPTION

The individual components of the subject device, SCHOELLY's NIR FI System, form a system to provide real-time endoscopic visible imaging (wight light imaging, WLI) and near-infrared (NIR) illumination and imaging (fluorescence imaging, FI) using indocyanine green (ICG):

- **Camera System** suitable for processing and recordings visible light images as well as NIR images. The Camera System consists of a Camera Control Unit (CCU) and a Camera Head for connection to a fiberoptic scope;
- **Light Source** and Light Guide for use with a fiberoptic scope for emitting light within the visible spectrum as well as in the NIR spectrum to cause fluorescence;
- **Fiberoptic Laparoscope** suitable for visible light and NIR light illumination and imaging;

The imaging agent (ICG) is not provided by SCHOELLY as part of the subject system.

F. INDICATIONS FOR USE

Camera System:

The Camera System is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery whenever a laparoscope/ endoscope/ arthroscope is indicated for use. A few examples of the more common endoscope surgeries are Laparoscopic cholecystectomy, Laparoscopic hernia repair, Laparoscopic appendectomy, Laparoscopic pelvic lymph node detection, Laparoscopically assisted hysterectomy, Laparoscopic and thorascopic anterior spinal fusion, Anterior cruciate ligament reconstruction, Knee arthroscopy, Small joint arthroscopy, Decompression fixation, Wedge resection, Lung biopsy, Pleural biopsy, Dorsal sympathectomy, Pleurodesis, Internal mammary artery dissection for coronary artery bypass, Coronary artery bypass grafting where endoscopic visualization is indicated and Examination of the evacuated cardiac chamber during performance of valve replacement. The users of the Camera System are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

NIR FI Light Source:

The NIR FI Light Source and NIR FI Light Guide are indicated for use to provide real-time endoscopic visible and near-infrared fluorescence imaging. The NIR FI Light Source and NIR FI Light Guide enable surgeons to perform minimally invasive surgery using standard endoscope visual 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 NIR FI Light Source and NIR FI Light Guide is 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.

G. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Styrker's predicate device, the AIM (Advanced Imaging Modality) System, was cleared in K182160. A detailed comparison of the proposed and predicate system is provided in the substantial equivalence table below. SCHOELLY's TipVision™ Videoscope System cleared in K201617 is cited as a reference device in this submission because it represents an example of a camera system with Product Code FET (endoscopic video imaging system/component) for use in different application fields (not just laparoscopy) and relying on basically the same image processing options for real-time endoscopic visible imaging as the Camera System of the subject device does. The TipVision™ Videoscope System does not include near-infrared fluorescence imaging capability and features an integrated camera head (Videoscope) instead of a camera head connected to a fiberoptic scope.

Table 15.1: Technological Characteristics Comparison Table

Attribute	**Proposed System SCHOELLY's NIR FI System (current submission)**	**Predicate System Styrker's AIM (Advanced Imaging Modality) System (K182160)**	**Similarities and Differences**
Intended Use	Endoscopic visible and near-infrared light illumination and imaging	Endoscopic visible and near-infrared light illumination and imaging	Same
Indications for Use	NOTE 1	NOTE 2	Camera System: Same Light Source: Same; Light source of subject device comprises a subset of the indications for use of the predicate device since subject device is not intended to transilluminate the ureter during open or laparoscopic surgical procedures
Imaging Modes	White Light NIR - fluorescence	White Light NIR – fluorescence NIR – transillumination	Same; Subject device comprises a subset of imaging modes as compared to predicate device since subject device is not intended to transilluminate the ureter during open or laparoscopic surgical procedures
Safety Standards	IEC 60601-1 IEC 60601-2-18 IEC 60601-1-2 IEC 60825-1	IEC 60601-1 IEC 60601-2-18 IEC 60601-1-2 IEC 60825-1	Same
System Components	Camera System, Light Source and Light Guide, Laparoscopes	Camera System; Light Source and SafeLight Cable; Laparoscope; IRIS Ureteral Kit; Imaging Agent Kits	Same; Subject system comprises a subset of components as compared to predicate system since imaging agents kits are not within the scope of delivery of the subject system
Use Environment	Hospital, Operating room	Hospital, Operating room	Same

Camera System			
Principles of Operation	Via an optical scope, light is transferred to imaging sensors of the camera system and the optical signal is transferred into an electrical signal. Imaging sensors acquire a continuous stream of image data which is further processed for proper viewing on displays.	Via an optical scope and coupler, light is transferred to imaging sensors of the camera system and the optical signal is transferred into an electrical signal. Imaging sensors acquire a continuous stream of image data which is further processed for proper viewing on displays.	Same
Image Sensor	CMOS image sensor	CMOS image sensor	Same
Image Processing / Video Output	Digital	Digital	Same
Data record and storage	Capture images and video recordings to USB or recordings to remote device	Capture images and video recordings to remote device	Similar
Resolution	up to 3840 x 2160	up to 3840 x 2160	Same
Resprocessing	Camera head released for manual or automated cleaning and sterilization	Camera head released for manual or automated cleaning and sterilization	Same
Light Source			
Principles of Operation	An electronic driver controls Red/Green/Blue LEDs & a near-infrared laser diode which are combined through. dichroic mirrors and projected onto an output light collimator. A fiber output bundle can be inserted into the light source to couple light to the distal end and into an endoscope.	An electronic driver controls Red/Green/Blue LEDs & a near-infrared laser diode which are combined through. dichroic mirrors and projected onto an output light collimator. A fiber output bundle can be inserted into the light source to couple light to the distal end and into an endoscope.	Same
Light Source / Laser	RGB LEDs Infrared Laser	RGB LEDs Infrared Laser	Same
Automatic light control	yes	yes	Same

NOTE 1:

Camera System:

The Camera System is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery whenever a laparoscope/ endoscope/ arthroscope is indicated for use. A few examples of the more common endoscope surgeries are Laparoscopic cholecystectomy, Laparoscopic hernia repair, Laparoscopic appendectomy, Laparoscopic pelvic lymph node detection, Laparoscopically assisted hysterectomy, Laparoscopic and thorascopic anterior spinal fusion, Anterior cruciate ligament reconstruction, Knee arthroscopy, Small joint arthroscopy, Decompression fixation, Wedge resection, Lung biopsy, Pleural biopsy, Dorsal sympathectomy, Pleurodesis, Internal mammary artery dissection for coronary artery bypass, Coronary artery bypass grafting where endoscopic visualization is indicated and Examination of the evacuated cardiac chamber during performance of valve replacement. The users of the Camera System are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

NIR FI Light Source:

The NIR FI Light Source and NIR FI Light Guide are indicated for use to provide real-time endoscopic visible and near-infrared fluorescence imaging. The NIR FI Light Source and NIR FI Light Guide enable surgeons to perform minimally invasive surgery using standard endoscope visual 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 NIR FI Light Source and NIR FI Light Guide is 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.

NOTE 2:

1688 4K Camera System with Advance Imaging Modality:

The 1688 Video Camera is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery whenever a laparoscope/ endoscope/ arthroscope is indicated for use. A few examples of the more common endoscope surgeries are Laparoscopic cholecystectomy, Laparoscopic hernia repair, Laparoscopic appendectomy, Laparoscopic pelvic lymph node detection, Laparoscopically assisted hysterectomy, Laparoscopic and thorascopic anterior spinal fusion, Anterior cruciate ligament reconstruction, Knee arthroscopy, Small joint arthroscopy, Decompression fixation, Wedge resection, Lung biopsy, Pleural biopsy, Dorsal sympathectomy, Pleurodesis, Internal mammary artery dissection for coronary artery bypass, Coronary artery bypass grafting where endoscopic visualization is indicated and Examination of the evacuated cardiac chamber during performance of valve replacement. The users of the 1688 Video Camera are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

L11 LED Light Source with Advanced Imaging Modality:

The L11 AIM Light Source and SafeLightTM Cable are indicated for use to provide real-time endoscopic visible and near-infrared fluorescence imaging. The L11 AIM Light Source and SafeLight Cable enable surgeons to perform minimally invasive surgery using standard endoscope visual 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 L11 AIM Light Source and SafeLight Cable is 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 L11 AIM Light Source is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.

Differences in technological characteristics do not raise different questions of safety and effectiveness.

H. PERFORMANCE DATA

The following performance testing has been performed for the subject device:

Reprocessing validation

Reprocessing validations were designed and conducted in accordance with FDA's 2015 guidance (including Appendix E revised June 2017) *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.*

Cleaning studies were designed and performed in accordance with AAMI TIR12:2010 *Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers*, AAMI TIR30:2011(R)2016 *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable devices*.

Sterilization studies were designed and performed in accordance with AAMI TIR12:2010 *Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers,* and ANSI/AAMI/ISO 17665-1:2006 (R)2013 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*. Cleaning and sterilization processes are defined in the device labeling per ISO 17664:2017 *Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices.*

These tests demonstrated that the device successfully passed cleaning, drying and sterilization validations according to the instructions in the user manual.

Software Documentation

Software documentation for a MODERATE Level of Concern device is provided in support of the proposed device per FDA's 2005 *Guidance for the Content of Premarket Submissions for Software Contained in Medical Device*. The software lifecycle, including software documentation and validation, is managed in accordance with IEC 62304:2006/A1:2016 *Medical Device Software – Software Life Cycle Processes*.

Electrical Safety Testing

The NIR FI System was assessed for conformity with, and was found to comply with, the relevant requirements of IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (ed. 3.1, including the US deviations) *Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance*.

The NIR FI System was assessed for conformity with, and was found to comply with, the relevant requirements of IEC 60601-2-18:2009 (ed. 3): *Medical Electrical Equipment, Part 2: Particular Requirements for the Basic Safety and Essential Performance of Endoscopic Equipment*.

Electromagnetic Compatibility Testing

The NIR FI System was assessed for conformity with, and was found to comply with, the relevant requirements of IEC 60601-1-2:2014 (ed. 4) *Medical Electrical Equipment, Part 1-2: General Requirements for Safety – Collateral standard: Electromagnetic Compatibility – Requirements and Tests*.

Non-Clinical Performance Testing

Non-Clinical performance test data demonstrate that the proposed NIR FI System performs substantially equivalent to the Stryker predicate AIM System and that the design output meets the design input requirements for endoscopic white light and near-infrared fluorescence imaging.

I. CONCLUSION

Based on a comparison of the proposed SCHOELLY NIR FI System and the Stryker predicate AIM System in terms of indications for use, physical and technological characteristics, and performance specifications the SCHOELLY NIR FI System raises no new issues of safety and effectiveness and is substantially equivalent to the predicate device.