June 20, 2024

Schoelly Fiberoptic GmbH
% Pamela Papineau
RAC
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K233225
Trade/Device Name: SCHOELLY Oxygen Saturation Imaging (OSI) Camera System (Camera Control Unit, Camera Head to be coupled to a fiberoptic scope)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, FET, PEA, MUD, NWB
Dated: September 27, 2023
Received: September 28, 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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Tanisha L. Hithe -S
Digitally signed by Tanisha L. Hithe -S
Date: 2024.06.20 14:59:25 -04'00'

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

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)*
K233225

Device Name
SCHOELLY Oxygen Saturation Imaging (OSI) Camera System

Indications for Use *(Describe)*
The SCHOELLY Oxygen Saturation Imaging (OSI) Camera System (consisting of Camera Control Unit and Camera Head) is used for endoscopic observation, diagnosis, treatment, and image recording. It is intended to process signals transmitted from a fiberoptic endoscope that is connected to the Camera Head.
This product may be used on all patients requiring endoscopic examination using SCHOELLY Laparoscopes and FUJIFILM's light source BL-7000X together with monitor, recorder and various peripheral devices. BLI (Blue Light Imaging) and LCI (Linked Color Imaging) are adjunctive tools which can be used to supplement white light endoscopy. BLI and LCI are not intended to replace histopathological sampling as a means of diagnosis.
The SCHOELLY OSI Camera System is further intended for use as an adjunctive monitor of the hemoglobin oxygen saturation of blood in superficial tissue of the endoscopic observation image area in patients at risk for ischemic states. The prospective clinical value of measurements made with OSI has not been demonstrated in disease states.

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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Schoelly Fiberoptic GmbH 13 June 2024

510(k) Summary

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: 13 June 2024

B. DEVICE IDENTIFICATION

The subject device is the SCHOELLY Oxygen Saturation Imaging (OSI) Camera System:

Trade Name	SCHOELLY Oxygen Saturation Imaging (OSI) 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 **Subsequent Product Codes**	GCJ FET, PEA, MUD, NWB
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

Indications for Use

The SCHOELLY Oxygen Saturation Imaging (OSI) Camera System (consisting of Camera Control Unit and Camera Head) is used for endoscopic observation, diagnosis, treatment, and image recording.

It is intended to process signals transmitted from a fiberoptic endoscope that is connected to the Camera Head.

This product may be used on all patients requiring endoscopic examination using SCHOELLY Laparoscopes and FUJIFILM's light source BL-7000X together with monitor, recorder and various peripheral devices.

BLI (Blue Light Imaging) and LCI (Linked Color Imaging) are adjunctive tools which can be used to supplement white light endoscopy. BLI and LCI are not intended to replace histopathological sampling as a means of diagnosis.

The SCHOELLY OSI Camera System is further intended for use as an adjunctive monitor of the hemoglobin oxygen saturation of blood in superficial tissue of the endoscopic observation image area in patients at risk for ischemic states.

The prospective clinical value of measurements made with OSI has not been demonstrated in disease states.

C. PREDICATE DEVICES

FUJIFILM's Processor VP-7000, Image Processing Unit EX-0 and Light Source BL-7000X serve as the primary predicate device in this submission:

510(k) Sponsor: FUJIFILM Corporation
510(k) Number: K203717

Trade Name	Processor VP-7000 and Image Processing Unit EX-0; Light Source BL-7000X
Common Name	Endoscopic Video Imaging System/Component
Classification Names	• Laparoscope, General & Plastic Surgery • Endoscopic Video Imaging System/Component, Gastroenterology-Urology
Product Codes **Subsequent Product Codes**	GCJ FET, NTN, PEA, MUD, NWB
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 Gastroenterology/Urology

Schoelly Fiberoptic GmbH 13 June 2024

Indications for Use:

Processor VP-7000 and Image Processing Unit EX-0

The VP-7000 unit is used for endoscopic observation, diagnosis, treatment, and image recording. It is intended to process electronic signals transmitted from a video endoscope (a video camera in an endoscope).

This product may be used on all patients requiring endoscopic examination and when using a Fujinon/FUJIFILM medical endoscope and light source together with monitor, recorder and various peripheral devices. BLI (Blue Light Imaging), LCI (Linked Color Imaging) and FICE (Flexible spectral-Imaging Color Enhancement) are adjunctive tools for gastrointestinal endoscopic examination which can be used to supplement Fujifilm white light endoscopy. BLI, LCI and FICE are not intended to replace histopathological sampling as a means of diagnosis.

The Image Processing Unit EX-0 is an optional module intended for use as an adjunctive monitor of the hemoglobin oxygen saturation of blood in superficial tissue of the endoscopic observation image area in patients at risk for ischemic states.

This product may be used on all patients requiring endoscopic examination when using a Fujinon/FUJIFILM medical endoscope, video processor and light source together with monitor, recorder and various peripheral devices.

The prospective clinical value of measurements made with OSI has not been demonstrated in disease states.

Light Source BL-7000X:

The BL-7000X Light Source is used for endoscopic observation, diagnosis, treatment, and image recording. It is intended to provide illumination to an endoscope. The light source also functions as a pump to supply air through the endoscope while inside the body to assist in obtaining clear visualization to facilitate diagnostic examination.

The SCHOELLY NIR FI System serves as the secondary predicate device in this submission:

510(k) Sponsor: Schoelly Fiberoptic GmbH
510(k) Number: K221591

The secondary predicate device is specifically comprised of the flowing components:

Trade Name	Camera System (Camera Control Unit, Camera Head to be coupled to a fiberoptic scope)

Schoelly Fiberoptic GmbH 13 June 2024

Common Name	Video Camera (Camera Control Unit, Camera Head to be coupled to a fiberoptic scope)
Classification Names	• Laparoscope, General & Plastic Surgery • Endoscopic Video Imaging System/Component, Gastroenterology-Urology
Product Codes **Subsequent Product Codes**	GCJ FET, OWN, FCW
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 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.

D. REFERENCE DEVICE

The Spectros T-Stat™ 303 Microvascular Tissue Oximeter serves as the reference device in this submission:

510(k) Sponsor: Spectros Corporation
510(k) Number: K081233

Trade Name	T-Stat™ 303 Microvascular Tissue Oximeter
Common Name	Tissue Oximeter
Classification Names	Oximeter, Tissue Saturation
Product Codes **Subsequent Product Codes**	MUD
Regulation Numbers	21 CFR 870.2700
Regulation Name	Oximeter
Device Classification	Class II
Regulation Medical Specialty	Cardiovascular

Review Panels	Cardiovascular

Indications for Use:

The Spectros T-Stat™ 303 Microvascular Tissue Oximeter is intended for use as an adjunct monitor of the localized hemoglobin oxygen saturation of blood in the microvascular tissue spaces (StO2%) in infants, children, or adults at risk for reduced-flow and no-flow ischemic states. The prospective clinical value of measurements made with the T-Stat™ Oximeter has not been demonstrated in disease states. The T-Stat™ Oximeter should not be used as the sole basis for diagnosis or therapy.

E. DEVICE DESCRIPTION

The proposed SCHOELLY Oxygen Saturation Imaging (OSI) Camera System is comprised of the SCHOELLY OSI Camera Control Unit (CCU) and the SCHOELLY OSI Camera Head (CH). It is intended for real-time endoscopic imaging and may be used on all patients requiring endoscopic examination.

The proposed device is for use with SCHOELLY Laparoscopes - mounted to the SCHOELLY OSI CH, or a videoscope connected to the SCHOELLY OSI CCU, an endoscopic light source and light guide and optional further light guide accessories. Further optional accessories to complete the endoscopic system include a monitor, an image recorder and further peripheral input devices (keyboard, mouse, foot pedal, etc.).

The proposed SCHOELLY OSI Camera System is suitable for real-time endoscopic visible imaging (white light imaging, WLI) as well as for real-time visualization of tissue oxygen saturation (StO2) levels during minimally invasive surgery (oxygen saturation imaging, OSI).

F. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

A detailed comparison of the proposed SCHOELLY OSI Camera System and the predicate devices, FUJIFILM's Processor VP-7000, Image Processing Unit EX-0 and Light Source BL-7000X (primary predicate) and the SCHOELLY NIR FI System (secondary predicate), is provided in the substantial equivalence table below. The proposed device represents a new design variant of related components (CCU and CH) of the secondary predicate device while having additional OSI capability. It incorporates the same imaging modes (OSI, BLI, LCI) as the primary predicate and is released for its common use with the light source of the primary predicate thereby operating with the same light spectrum. The Spectros T-Stat™ 303 Microvascular Tissue Oximeter cleared for marketing by FDA in K081233 is cited as a reference device as another example of tissue oximetry.

Table 15.1: Technological Characteristics Comparison Table

Attribute	**Proposed device SCHOELLY's OSI Camera** **(current submission)**	**Primary predicate device FUJIFILM's Processor VP-7000, Image Processing Unit EX-0, Light Source BL-7000X** **(K203717)**	**Secondary predicate device SCHOELLY's NIR FI System** **(K221591)**	**Similarities and Differences**
Manufacturer	SCHOELLY Fiberoptic	FUJIFILM Corporation	SCHOELLY Fiberoptic	N/A
Device Name	SCHOELLY Oxygen Saturation Imaging (OSI) Camera System	Processor VP-7000 and Image Processing Unit EX-0; Light Source BL-7000X	NIR FI System	N/A
510(k) Number	Current submission	K203717	K221591	N/A
Regulation Number and Name	876.1500 Endoscope and Accessories,	876.1500 Endoscope and Accessories	876.1500 Endoscope and Accessories	Same
Review Panel	Gastroenterology/Urology General & Plastic Surgery	Gastroenterology/Urology General & Plastic Surgery	Gastroenterology/Urology General & Plastic Surgery	Same
Product Codes	GCJ, FET, PEA, MUD, NWB	GCJ FET, NTN, PEA, MUD, NWB	GCJ FET, OWN, FCW	Similar; Subject device compromises a subset of product codes of predicate devices according to respective system components and features
Indications for Use	see Section B	see Section C	see Section C	See predicate device information sections above
System Components	Camera Control Unit, Camera Head to be coupled to a fiberoptic scope for use with light source and further light source accessories.	Camera Control Unit, Image Processing Unit , Light Source for use with videoscopes and further light source accessories.	Camera Control Unit, Camera Head to be coupled to a fiberoptic scope, Fiberoptic Scope and Light Source for use with light guide and further light guide accessories.	Similar; Subject system comprises a subset of components as compared to predicate devices
Principles of Operation	Light emitted by an external light source is transferred via fiber bundles into the body and an image	Light emitted by an external light source is transferred via fiber bundles into the body and an image (transferred back via	Light emitted by an external light source is transferred via fiber bundles into the body and an image (transferred back via a	Similar. See Device Description and predicate device information above

	(transferred back via a fiberoptic system) is captured by a camera where an optical signal changes to an electrical signal. Imaging sensors acquire a continuous stream of image data which is further processed for proper viewing on displays.	a fiberoptic /electrical system) is captured by a camera. Imaging sensors acquire a continuous stream of image data which is further processed for proper viewing on displays.	fiberoptic system) is captured by a camera where an optical signal changes to an electrical signal. Imaging sensors acquire a continuous stream of image data which is further processed for proper viewing on displays.	
Power Rating (CCU)	100 - 240 V ~ 50/60 Hz	100 - 240 V ~ 50/60 Hz	100 - 240 V ~ 50/60 Hz	Same
Image Sensor	CMOS image sensor	CMOS image sensor, CCD image sensor	CMOS image sensor	Similar
Dimensions (CCU)	370 x 140 x 391 mm	390 x 110 x 485 mm	295 x 129.5 x 355 mm (4K configuration)	Similar
Weight (CCU)	9 kg	9 kg	7 kg (4K configuration)	Similar
Imaging Modes	White Light Imaging (WLI) Oxygen Saturation Imaging (OSI) Blue Light Imaging (BLI, BLI-bright) Linked Color Imaging (LCI)	White Light Imaging (WLI) Oxygen Saturation Imaging (OSI) Blue Light Imaging (BLI, BLI-bright) Linked Color Imaging (LCI) Flexible Spectral-Imaging Color Enhancement (FICE)	White Light Imaging (WLI) NIR Fluorescence Imaging	Similar; Subject device comprises a subset of imaging modes as compared to predicate devices; Subject device does not provide FICE mode and NIR FI
Data record and storage	Capture images or video recordings	Capture images	Capture images and video recordings to USB or recordings to remote device	Similar
Image Processing / Video Output	Digital	Digital	Digital	Same
Resolution	up to 3840 x 2160	up to 1920 x 1080	up to 3840 x 2160	Similar; All devices provide at least Full HD resolution
Safety Standards	IEC 60601-1 IEC 60601-2-18	IEC 60601-1 IEC 60601-2-18	IEC 60601-1 IEC 60601-2-18	Similar;

	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2 IEC 60825-1	Subject device comprises a subset of safety standards compared to the primary predicate device in accordance with respective system components
Use Environment	Hospital, Operating room	Hospital, Operating room	Hospital, Operating room	Same

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

G. 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 Guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (March 2015, including Appendix E revised June 2017)* .

Cleaning and sterilization studies were designed and performed in accordance with ANSI/ AAMI ST98:2022 and ISO 14937:2009. Cleaning and sterilization processes are defined in the device labeling as per ISO 17664:2017.

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

Software Documentation

Software documentation for a Basic Documentation Level is provided in support of the proposed device per FDA's Guidance *Content of Premarket Submissions for Device Software Functions: Guidance for Industry and FDA Staff (June 2023)*. The software lifecycle, including software documentation and validation, is managed in accordance with IEC 62304:2006 + A1:2016.

Electrical Safety and Electromagnetic Compatibility Testing

The OSI Camera System was assessed for conformity with, and was found to comply with the relevant requirements of IEC 60601-1:2005+AM1:2012, IEC 60601-1-2:2014, IEC 60601-1-2:2020, and IEC 60601-2-18:2009.

Non-Clinical Performance Testing

Non-clinical testing of the proposed device's imaging modes was conducted with its WLI, BLI and LCI modes to assess image sharpness, depth of field, signal-to noise ratio, temporal noise, color reproduction, dynamic range, distortion, contrast enhancement, and artifacts. The results showed that the device could accurately reproduce reference images used for assessing these image characteristics. OSI testing included measurements regarding oxygen saturation accuracy, the effect of distance, angle and orientation, and the effect of temperature and duration, as well as the measurement of two-dimensional StO2 variation. The proposed SCHOELLY OSI Camera System and the primary predicate device's output were compared to the reference device with measurements on a tissue phantom with controlled oxygen levels. The results showed that the oxygen saturation values produced by the SCHOELLY device were similar to those produced by the primary predicate. Images of the human oral cavity and hand were also acquired to provide a side-by-side comparison of the SCHOELLY OSI mode and the primary predicate device's oximetry mode. The results demonstrated that the SCHOELLY OSI Camera System produced similar images compared to predicate device. In addition, comparisons of intestines and stomach images from an in-vivo animal study were made for the WLI, BLI, LCI, and OSI modes, and the comparisons showed that

the SCHOELLY device produced images that were similar to those produced by the primary predicate device. The combination of bench testing and results from in-vivo animal and human testing support that the SCHOELLY device can produce images of similar intensity, color, contrast, and tissue oxygenation, compared to those produced by the primary predicate device and the results support substantial equivalence.

H. CONCLUSION

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