April 1, 2022

Saneso Inc.
% Parul Chansoria
Founder and CEO
Elexes Medical Consulting, LLC
30 N Gould St Ste R
Sheridan, WY 82801

Re: K210052
Trade/Device Name: Saneso Colonoscope 360-A (Model: with/without Select Band Imaging (SBI) and with/without Dual Band Imaging (DBI)), Saneso Single Camera Colonoscope-A (Model: with/without Select Band Imaging (SBI)), Saneso Gastroscope 360-A (Model: with/without Select Band Imaging (SBI) and with/without Dual Band Imaging (DBI)), Saneso Single Camera Gastroscope-A (Model: with/without Select Band Imaging (SBI))
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDF, FDS, FET, NWB
Dated: February 25, 2022
Received: March 2, 2022

Dear Parul Chansoria:

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,

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K210052

Device Name
Saneso -A Series {(Saneso Colonoscope 360-A (Model: with and without SBI/DBI), Saneso Single Camera Colonoscope-A (Model: with and without SBI), Saneso Gastroscope 360-A (Model: with and without SBI/DBI), Saneso Single Camera Gastroscope-A (Model: with and without SBI)}

Indications for Use *(Describe)*
The Saneso Colonoscope 360-A is intended for diagnostic visualization of the lower gastrointestinal tract (including the rectum, colon and cecum) and Saneso Colonoscope 360-A is not indicated for ileoscopy procedures. The system also provides access for therapeutic interventions using standard endoscopy tools. The Saneso system consists of Saneso Colonoscope 360-A, Saneso Processor-A and other ancillary equipment.

The Saneso Gastroscope 360-A is intended for diagnostic visualization of the upper gastrointestinal tract (including the esophagus, stomach and duodenum). The system also provides access for therapeutic interventions using standard endoscopy tools. The Saneso system consists of Saneso Gastroscope 360-A/Saneso Single Camera Gastroscope-A, Saneso Processor-A and other ancillary equipment.

The Saneso Single Camera Colonoscope-A is intended for diagnostic visualization of the lower gastrointestinal tract (including the rectum, colon and ileocecal valve). The system also provides access for therapeutic interventions using standard endoscopy tools. The Saneso system consists of Saneso Colonoscope 360-A/Saneso Single Camera Colonoscope-A, Saneso Processor-A and other ancillary equipment.

The Saneso Single Camera Gastroscope-A is intended for diagnostic visualization of the upper gastrointestinal tract (including the esophagus, stomach and duodenum). The system also provides access for therapeutic interventions using standard endoscopy tools. The Saneso system consists of Saneso Gastroscope 360-A/Saneso Single Camera Gastroscope-A, Saneso Processor-A and other ancillary equipment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

This 510(k) Summary has been created per the requirements of the Safe Medical Device Act (SMDA) of 1990, and the content is provided in conformance with 21 CFR Part 807.92.

5.1. Submitter's Information

Saneso, Inc.
One Oxford Center, 301 Grant Street Suite 4300
Pittsburgh, PA 15219

Contact Person:

Parul Chansoria, MS, RAC, CQA
CEO & Founder, Elexes Medical Consulting
Telephone: +408-475-8091
Email: parul@elexes.com
Summary prepared:

5.2. Device Information

5.2.1. Common name: Colonoscope, Video
Trade name: Saneso Colonoscope 360-A (Model: with/without Select Band Imaging (SBI) and with/without Dual Band Imaging(DBI)), Saneso Single Camera Colonoscope-A (Model: with/without Select Band Imaging (SBI))
Classification name: Endoscope and Accessories
Regulatory class: Class II
Classification panel: Gastroenterology/Urology
Product code: FDF, FET, NWB
Regulation number: 876.1500

5.2.2. Common name: Gastroscope, Video
Trade name: Saneso Gastroscope 360-A (Model: with/without Select Band Imaging (SBI) and with/without Dual Band Imaging(DBI)), Saneso Single Camera Gastroscope-A (Model: with/without Select Band Imaging (SBI))
Classification name: Endoscope and Accessories
Regulatory class: Class II
Classification panel: Gastroenterology/Urology
Product code: FDS, FET, NWB
Regulation number: 876.1500

Saneso
Endoscopy Reinvented™

5.3. Predicate Device Information

Saneso Colonoscope 360-A (Model: With and Without SBI/DBI) is substantially equivalent to the following cleared device:

Company	Predicate Priority	Product	510(k) Number
Shirakawa Olympus Co., Ltd	Primary	EVIS EXERA II Colonovideoscope CF-H180AL	K100584
Olympus Optical Co. Ltd.	Reference Device	Evis Exera 140 System PCF 140L	K954451

Saneso Gastroscope 360-A (Model: With and Without SBI/DBI) is substantially equivalent to the following cleared device:

Company	Predicate Priority	Product	510(k) Number
Shirakawa Olympus Co., Ltd	Primary	Evis Exera II Gastrointestinal Videoscope GIF-H180	K100584
Olympus Optical Co. Ltd.	Reference Device	Evis Exera 140 System GIF 140	K954451

The Saneso Single Camera Colonoscope-A (Model: With and Without SBI) is equivalent to the following FDA-cleared device:

Company	Predicate priority	Product	510(k) Number
Shirakawa Olympus Co., Ltd	Primary	EVIS EXERA II Colonovideoscope (PCF Q180AL)	K100584

The Saneso Single Camera Gastroscope-A (Model: With and Without SBI) is equivalent to the following FDA-cleared device:

Company	Predicate priority	Product	510(k) Number
Shirakawa Olympus Co., Ltd	Primary	Evis Exera II GIF-H180	K100584

5.4. Device Description

Saneso Colonoscope 360-A (Model: With and Without SBI/DBI)

The Saneso Colonoscope 360-A is an endoscopic platform for diagnostic visualization and therapeutic access to the lower gastrointestinal tract (including the anus, rectum, sigmoid colon, colon and cecum) and Saneso Colonoscope 360-A is not indicated for ileoscopy procedures. The system enables physicians to view a high resolution wide field of view of up to 360°. The system consists of Saneso camera heads, colonoscope, video system, light source and other ancillary equipment. The Saneso Colonoscope 360-A is a full circular view video colonoscope and features multiple viewing options: 5 camera 360-degree raw images, 5 camera-stitched 360-degree images, and forward only view modes. The selection is made through the video interface.

The Saneso Colonoscope 360-A must be used in conjunction with the Saneso Processor-A. The Saneso Processor-A system serves as a control platform for the Saneso Colonoscope 360-A. The processor box consists of the electronics and mechanics required to operate the endoscope. It is responsible for image processing, transferring video signals from the colonoscope, pneumatic control, and control of various external accessories that interface with the system. The accessories include the foot pedal, which is used to control the tissue wash water, the mouse, and the keyboard which are used for interfacing with the software and changing settings as needed. There are two monitors which can be connected, i.e. the master monitor and the slave monitor. The master monitor can be used for viewing and interfacing with controls on the image processor and the slave monitor is used only for viewing purposes.

The device is equipped with five cameras in order to provide a maximum 360° field of view (FOV) with high resolution video using external monitors connected through display ports. Each camera has LED light sources enabling the user to visualize in white light and other user selectable spectrum with Select Band Imaging or Dual Band

Imaging modes (applicable only with SBI/DBI). The system is configured to transfer data to an external HL7 compliant electronic health record system. The system can be controlled using a mouse and keyboard.

Saneso Gastroscope 360-A (Model: With and Without SBI/DBI)

The Saneso Gastroscope 360-A is an endoscopic platform for diagnostic visualization and therapeutic access to the upper gastrointestinal tract (including the esophagus, stomach and duodenum). The system enables physicians to view a high resolution wide field of view of up to 360°. The system consists of Saneso camera heads, gastroscope, video system, light source and other ancillary equipment. The Saneso Gastroscope 360-A is a full circular view video gastroscope and features multiple viewing options: 5 camera 360-degree raw images, 5 camera-stitched 360-degree images and forward only view modes. The selection is made through the video interface.

The Saneso Gastroscope 360-A must be used in conjunction with the Saneso Processor-A. The Saneso Processor-A system serves as a control platform for the Saneso Gastroscope 360-A. The processor box consists of the electronics and mechanics required to operate the endoscope. It is responsible for image processing, transferring video signals from the gastroscope, pneumatic control, and control of various external accessories that interface with the system. The accessories include the foot pedal, which is used to control the tissue wash water, the mouse and the keyboard which are used for interfacing with the software and changing settings as needed. There are two monitors which can be connected, i.e. the master monitor and the slave monitor. The master monitor can be used for viewing and interfacing with controls on the image processor and the slave monitor is used only for viewing purposes.

The device is equipped with five cameras in order to provide a maximum 360° field of view (FOV) with high resolution video using external monitors connected through display ports. Each camera has LED light sources enabling the user to visualize in white light and other user selectable spectrum with select either single band imaging or dual band imaging modes (applicable only with SBI/DBI). The system is configured to transfer data to an external HL7 compliant electronic health record system. The data is transferred using Wi-Fi or Ethernet. The system can be controlled using a mouse and keyboard.

Saneso Single Camera Colonoscope-A (Model: With and Without SBI)

The Saneso Single Camera Colonoscope-A is an endoscopic platform that provides diagnostic visualization and therapeutic access to the lower gastrointestinal tract including the rectum, colon and ileocecal valve. The system employs Select Band Imaging mode. The Saneso Single Camera Colonoscope-A features a single camera at

the distal end that offers a 140° Field of View. The distal end features the front camera, LED light assembly, instrument channel outlet, nozzle, tissue wash outlet.

The Saneso Single Camera Colonoscope-A comprises programmable control buttons, insertion tube, suction valve, air/water valve, instrument channel port, umbilical cord, connector, angulation knobs and the bending section.

The Saneso Single Camera Colonoscope-A must be used in conjunction with Saneso Processor-A. The Saneso Processor-A is preinstalled with the Saneso Image Processing software and serves as a control platform for the Saneso Single Camera Colonoscope-A. The Saneso Processor processes the image and relays the video signals from the colonoscope to external display monitors. The Saneso Processor also offers pneumatic/water controls and interfaces for insufflation, tissue irrigation and camera lens wash. The Saneso processor also controls various external accessories that interface with the system. The software is operated via a mouse and keyboard. Two monitors are connected to the system i.e a master monitor and slave monitor. The master monitor can be used for viewing and interfacing with controls on the image processor and the slave monitor is used only for viewing purposes.

Saneso Single Camera Gastroscope-A (Model: With and Without SBI)

The Saneso Single Camera Gastroscope-A is an endoscopic platform that provides diagnostic visualization and therapeutic access to the upper Gastrointestinal (G.I) tract including the esophagus, stomach and duodenum. The system employs Select Band Imaging mode. The Saneso Single Camera Gastroscope-A consists of the Saneso Single Camera Gastroscope-A which is used in conjunction with the Saneso Processor-A and other ancillary equipment. The gastroscope features a single camera at the distal end that offers a 140° Field of View. The distal end features the front camera, LED light assembly, instrument channel outlet, nozzle, tissue wash outlet.

The Saneso Single Camera Gastroscope-A comprises programmable control buttons, insertion tube, suction valve, air/water valve, instrument channel port, umbilical cord, connector, angulation knobs and the bending section.

The Saneso Single Camera Gastroscope-A must be used in conjunction with Saneso Processor-A. The Saneso Processor-A is preinstalled with the Saneso Image Processing Software and serves as a control platform for the Saneso Single Camera Gastroscope-A. The Saneso Processor processes the image and relays the video signals from the colonoscope to external display monitors. The Saneso Processor also offers pneumatic/water controls and interfaces for insufflation, tissue irrigation and camera lens wash. The Saneso processor also controls various external accessories that interface with the system. The software is operated via a mouse and keyboard. Two monitors are connected to the system i.e a master monitor and slave monitor. The master monitor can

be used for viewing and interfacing with controls on the image processor and the slave monitor is used only for viewing purposes.

5.5. Indications for Use

Saneso Colonoscope 360-A

The Saneso Colonoscope 360-A is intended for diagnostic visualization of the lower gastrointestinal tract (including the rectum, colon and cecum) and Saneso Colonoscope 360-A is not indicated for ileoscopy procedures. The system also provides access for therapeutic interventions using standard endoscopy tools. The Saneso system consists of Saneso Colonoscope 360-A, Processor- A and other ancillary equipment.

Saneso Gastroscope 360-A

The Saneso Gastroscope 360-A is intended for diagnostic visualization of the upper gastrointestinal tract (including the esophagus, stomach and duodenum). The system also provides access for therapeutic interventions using standard endoscopy tools. The Saneso system consists of Saneso Gastroscope 360-A, Processor-A and other ancillary equipment.

Saneso Single Camera Colonoscope-A

The Saneso Single Camera Colonoscope is intended for diagnostic visualization of the lower gastrointestinal tract (including the rectum, colon and ileocecal valve). The system also provides access for therapeutic interventions using standard endoscopy tools. The Saneso system consists of Saneso Single Camera Colonoscope, Processor-A and other ancillary equipment.

Saneso Gastroscope 360- A

The Saneso Single Camera Gastroscope is intended for diagnostic visualization of the upper gastrointestinal tract (including the esophagus, stomach and duodenum). The system also provides access for therapeutic interventions using standard endoscopy tools. The Saneso system consists of Saneso Single Camera Gastroscope, Processor-A and other ancillary equipment.

5.6. Technological Characteristics

Saneso Colonoscope 360-A (Model: With and Without SBI/DBI)

The Indications for Use, key technological characteristics and operating principle of the Subject Device (Saneso Colonoscope 360-A (Model: With and Without SBI/DBI)) is equivalent to the Predicate Device and Reference Device.

5.6.1. Saneso Colonoscope 360-A (With and Without SBI/DBI) vs. EVIS EXERA II Colonovideoscope CF-H180AL (K100584)

Table 1: Substantial Equivalence Table for Saneso Colonoscope 360-A (With and Without SBI/DBI)

Parameter	Subject Device: Saneso Colonoscope 360-A (With and Without SBI/DBI)	Predicate: EVIS EXERA II Colonovideoscope CF-H180AL(K100584)	Reference Device Evis Exera 140 System PCF 140L	Equivalence
Manufacturer	Saneso, Inc.	Shirakawa Olympus Co., Ltd.	Olympus Optical Co. Ltd	---
Device Name	Saneso Colonoscope 360-A	EVIS EXERA II Colonovideoscope CF-H180AL	Evis Exera 140 System PCF 140L	---
510(k) Number	---	K100584	K954451	---
Classification Product Code/ Regulatory Number	FDF 876.1500	FDF 876.1500	FET (now known as FDF) 876.1500	**Equivalent**
Subsequent Product Code	FET, NWB	FDS	-	
Regulatory Class	II	II	II	**Equivalent**
Indications for use	The Saneso Colonoscope 360-A is intended for diagnostic visualization of the lower gastrointestinal tract (including the rectum, colon and cecum) and Saneso Colonoscope 360-A is not indicated for ileoscopy procedures.	These instruments have been designed to be used with an Olympus video System center, light source, documentation equipment, video monitor, endo-therapy accessories such as a biopsy forceps and	The Evis Exera 140 System PCF 140L is specifically designed for endoscopic diagnosis treatment and photo and video documentation in combination	**Equivalent**

	The system also provides access for therapeutic interventions using standard endoscopy tools. The Saneso system consists of Saneso Colonoscope 360-A, Saneso Processor-A and other ancillary equipment.	other ancillary equipment. Use the EVIS EXERA II Colonovideoscope CF-H180AL for endoscopy and endoscopic surgery within the lower digestive tract (including the anus, rectum, sigmoid colon, colon and ileocecal valve).	with Olympus endoscopes various accessories and ancillary equipment within the upper and lower digestive tract including the esophagus, stomach, pancreatic duct, biliary duct, duodenum, small intestine rectum, and, colon.	
Colonoscope Type	Flexible	Flexible	-	**Equivalent**
OTC/Rx	Rx	Rx	-	**Equivalent**
System Operating Ranges				
Operating Temperature	10°C (50F) - 40°C (104F)	10°C (50F) - 40°C (104F)	10°C (50F) - 40°C (104F)	**Equivalent**
Relative Humidity	85% maximum without condensation	30% - 85%	30% - 85%	**Equivalent**
Operating Range	120 V and 240V 60 Hz.	100V- 240V 50/60 Hz	100V- 240V 50/60 Hz	**Different**
Performance Characteristics				
Mode of Operation	The processor relays the image from the endoscope to a video monitor	The processor relays the image from the endoscope to a video monitor	The processor relays the image from the endoscope to a video monitor	**Equivalent**

Maximum Field of View	360°	170°	140°	**Different**
Depth of Field [mm] (Front camera)	2-100	2-100	5-100	**Equivalent**
Depth of Field [mm] (Side camera)	2-50	-	-	-
Working Length	168 cm	168 cm	133cm	**Equivalent**
Instrument Channel Inner Diameter	3.7 mm	3.7mm	3.2mm	**Equivalent**
Maximum Distal End Outer Diameter	15.6 mm	13.9mm	11.3mm	**Different**
Insertion Tube Outer Diameter	12.8 mm	12.8 mm	11.3mm	**Equivalent**
Bending Section: Angulation Range	Up/Down: 180° Left/Right: 160°	Up/Down: 180° Left/Right: 160°	Up/Down: 180° Left/Right: 160°	**Equivalent**
HD Technology	Yes	Yes	Yes	**Equivalent**
Processor Box Characteristics				
Digital Output (Display)	3 channels DVI	3 channels DVI	3 channels DVI	**Equivalent**
Control Signals	White balance A/W pump control LED control	White balance A/W pump control LED control	White balance A/W pump control LED control	**Equivalent**

Electrical Class	Class I, Type BF	Class I, Type BF	Class I, Type BF	**Equivalent**
LED Intensity Control	Yes	Yes	Yes	**Equivalent**
Enhancement Mechanism	White light, Select Band Imaging and Dual Band Imaging	White light and Narrow Band Imaging	Unknown	**Different with respect to Saneso Colonoscope 360-A with SBI/DBI and equivalent to Saneso Colonoscope 360-A without SBI/DBI**
Freeze/Release	Yes	Yes	Yes	**Equivalent**
CCD Type	Color	Color	Color	**Equivalent**

5.6.1.1. Similarities between Subject Device and Predicate Device

- The intended use is the same for the Subject and the Predicate Devices and both devices are meant for prescription use.
- The mode of operation is the same for the Subject and the Predicate Devices.
- The operating temperature and relative humidity for both devices is the same.
- The front camera depth of field is the same for the Subject and the Predicate Devices.
- The instrument channel inner diameter, insertion tube outer diameter is the same for the Subject and Predicate Devices.
- The working length is the same for the Subject and the Predicate Devices.

- The Angulation range is the same for the Subject and the Predicate Devices.
- The Electrical Class of both devices is the same.
- Both devices incorporate HD technology and use white light and Narrow Band Imaging as the Enhancement Mechanism.
- The processor box characteristics of both devices are the same in terms of display method, electrical class and features such as LED intensity control, zooming and freeze/release.

5.6.1.2. Differences

The differences between the Subject Device and the Predicate Devices do not raise new questions of safety and efficacy. Testing conducted by Saneso, Inc demonstrates that the Subject Device performs as intended.

Saneso Gastroscope 360-A

The Indications for Use, key technological characteristics and operating principle of the Subject Device (Saneso Gastroscope 360-A) is equivalent to the Predicate Device and Reference Device.

5.6.2. Saneso Gastroscope 360-A (Model: With and Without SBI/DBI) vs. Evis Exera II Gastrointestinal Videoscope GIF-H180 (K100584)

Table 2: Substantial Equivalence Table for Saneso Gastroscope 360-A (Model: With and Without SBI/DBI)

Title	Subject Saneso Gastroscope 360-A (Model: With and Without SBI/DBI)	Predicate: Evis Exera II Gastrointestinal Videoscope GIF-H180 (K100584)	Reference Device Evis Exera 140 System GIF 140	Equivalence
Manufacturer	Saneso, Inc.	Shirakawa Olympus Co., Ltd.	Olympus Optical Co. Ltd	---
Device Name	Saneso Gastroscope 360-A	Evis Exera II Gastrointestinal Videoscope GIF-H180	Evis Exera 140 System GIF 140	---

Saneso
Endoscopy Reinvented™

510(k) Number	---	K100584	K954451	**---**
Classification Product Code/ Regulatory Number	FDS 876.1500	FDS 876.1500	FET (now known as FDS) 876.1500	**Equivalent**
Subsequent Product Code	FET, NWB	FDS	-	
Regulatory Class	II	II	II	**Equivalent**
Indications for use	The Saneso Gastroscope 360-A is intended for diagnostic visualization of the upper gastrointestinal tract (including the esophagus, stomach and duodenum). The system also provides access for therapeutic interventions using standard endoscopy tools. The Saneso system consists of Saneso Gastroscope 360-A Saneso Processor-A and other ancillary equipment.	These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, endo-therapy accessories (such as a biopsy and other ancillary equipment). Use the EVIS EXERA II Gastrointestinal Videoscope GIF-H180, for endoscopy and endoscopic surgery within the upper digestive tract (including the esophagus, stomach, and duodenum).	The Evis Exera 140 System GIF 140 is specifically designed for Endoscopic Diagnosis, treatment and photo and video documentation in combination with Olympus endoscopes various accessories and Ancillary equipment within the upper and lower digestive tract including the Esophagus, Stomach, pancreatic duct, biliary duct, duodenum, small intestine rectum and, colon.	**Equivalent**
Gastroscope Type	Flexible	Flexible	Flexible	**Equivalent**
OTC/Rx	Rx	Rx	Rx	**Equivalent**

System Design and Operating Ranges				
Operating Temperature	10°C (50F) - 40°C (104F)	10°C (50°F) - 40°C (104°F)	10°C (50°F) - 40°C (104°F)	**Equivalent**
Relative Humidity	85% maximum without condensation	30% - 85%	30% - 85%	**Equivalent**
Performance Characteristics				
Operating Range	120 V and 240V 60 Hz.	100V- 240V 50/60 Hz	100V- 240V 50/60 Hz	**Different**
Mode of Operation	The processor relays the image from the endoscope to a video monitor	The processor relays the image from the endoscope to a video monitor	The processor relays the image from the endoscope to a video monitor	**Equivalent**
Maximum Field of View	360°	140°	120°	**Different**
Depth of Field (mm) (Front camera)	2-100	2-100	3-100	**Equivalent**
Depth of Field (mm) (Side camera)	2-50	-	-	**-**
Working Length (cm)	104	103	103	**Different**
Instrument Channel Inner Diameter (mm)	3.7	2.8	2.8	**Different**
Maximum Distal End Outer Diameter (mm)	15.6	9.8	9.8	**Different**
Insertion Tube Outer Diameter(mm)	12.8	9.8	9.8	**Different**

Bending Section: Angulation Range	Up/Down: 180° Left/Right: 160°	Up/Down: 210°/90° Left/Right: 100°/100°	Up/Down: 210°/90° Left/Right: 100°/100°	**Different**
HD Technology	Yes	Yes	Yes	**Equivalent**
Processor Box Characteristics				
Digital Output (Display)	3 channels DVI	3 channels DVI	3 channels DVI	**Equivalent**
Control Signals	White balance A/W pump control LED control	White balance A/W pump control LED control	White balance A/W pump control LED control	**Equivalent**
Electrical Class	Class I, Type BF	Class I, Type BF	Class I, Type BF	**Equivalent**
LED Intensity Control	Yes	Yes	Yes	**Equivalent**
Enhancement Mechanism	White light, Select Band Imaging and Dual Band Imaging	White light and Narrow Band Imaging	None	**Different with respect to Saneso Gastroscope 360-A with SBI/DBI and equivalent to Saneso Gastroscope 360-A without SBI/DBI**
Freeze/ Release	Yes	Yes	Yes	**Equivalent**
CCD Type	Color	Color	Color	**Equivalent**

5.6.2.1. Similarities between Subject Device and Predicate Device

- The intended use is the same for the Subject and the

Predicate Devices and both devices are meant for prescription use.

- The mode of operation is the same for the Subject and the Predicate Device.
- The operating temperature and relative humidity for both devices is the same.
- The front camera depth of field is the same for the Subject and the Predicate Device.
- The Electrical Class of both devices is the same.
- Both devices incorporate HD technology and use white light and Narrow Band Imaging as the Enhancement Mechanism.
- The processor box characteristics of both devices are the same in terms of display method, electrical class and features such as LED intensity control, zooming and freeze/release.

5.6.2.2. Differences

The differences between the Subject Device and the Predicate Devices do not raise new questions of safety and efficacy. Testing conducted by Saneso, Inc, demonstrates that the Subject Device performs as intended.

5.6.3. Saneso Single Camera Colonoscope-A (Model: With and Without SBI) Vs EVIS EXERA II Colonovideoscope PCF-Q180AL

Table 3: Substantial Equivalence table for Saneso Single Camera Colonoscope-A (Model: With and Without SBI)

Parameter	Subject Device: Saneso Single Camera Colonoscope (Model: With and Without SBI)	Predicate Device: EVIS EXERA II Colonovideoscope PCF-Q180AL	Equivalence
Manufacturer	Saneso, Inc.	Shirakawa Olympus Co., Ltd	-
Device Name	Saneso Single Camera Colonoscope-A	EVIS EXERA II Colonovideoscope	-

		PCF-Q180AL	
510(k) Number	-	K100584	-
Classification Product Code/Regulator Number	FDF 876.1500	FDF 876.1500	
Subsequent Product Code	FET, NWB	FDS	
Regulatory Class	II	II	**Equivalent**
Indications for Use	The Saneso Single Camera Colonoscope-A is intended for diagnostic visualization of the lower gastrointestinal tract including the rectum, colon and ileocecal valve. The system also provides access for therapeutic interventions using standard endoscopy tools. The Saneso system consists of Saneso Single Camera Colonoscope-A, Saneso Processor- A and other ancillary equipment.	These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories such as a biopsy forceps and other ancillary Equipment. Use the EVIS EXERA II Colonovideoscope PCF-Q180AL for endoscopy and endoscopic surgery within the lower digestive tract (including the anus, rectum, sigmoid colon, colon and ileocecal valve).	**Equivalent**
Colonoscope type	Flexible	Flexible	**Equivalent**
OTC/Rx	Rx	Rx	**Equivalent**
System Operating Ranges			
Operating Temperature	10℃ - 40℃	10℃ - 40℃	**Equivalent**
Relative Humidity	85% maximum without condensation	30% - 85%	**Equivalent**
Operating Range	120V and 240V 60Hz	100V - 240 V(50/60 Hz)	**Different**

Performance Characteristics			
Mode of Operation	The Processor relays video signals from the endoscope to a video monitor.	The Processor relays video signals from the endoscope to a video monitor.	**Equivalent**
Maximum Field of View	140°	140°	**Equivalent**
Depth of Field [mm]	2 - 100 mm	3 - 100 mm	**Different**
Working Length	168 cm	168 cm	**Equivalent**
Instrument Channel Inner Diameter	3.7 mm	3.2 mm	**Different**
Maximum Distal End Outer Diameter	11.6 mm	11.3 mm	**Different**
Insertion Tube Outer Diameter	11.8 mm	11.5 mm	**Different**
Bending Section: Angulation Range	Up/Down: 180° Left/Right: 160°	Up/Down: 180° Left/Right: 160°	**Equivalent**
HD Technology	Yes	Yes	**Equivalent**
Processor Box Characteristics			
Digital Output (Display)	3 channels DVI	3 channels DVI	**Equivalent**
Control Signals	White balance A/W pump control Light control	White balance A/W pump control Light control	**Equivalent**
Electrical Class	Class I, Type BF	Class I, Type BF	**Equivalent**
Light Intensity Control	Yes	Yes	**Equivalent**
Enhancement Mechanism	Yes (White Light with Select Band Imaging)	Yes (White Light and Narrow Band Imaging)	**Equivalent with respect**

			to Saneso Single Camera Colonoscope-A with/without SBI
Freeze/Release	Yes	Yes	**Equivalent**
CCD Type	Colour	Colour	**Equivalent**

5.6.3.1. Similarities

- The intended use is the same for the Subject Device and Predicate Device.
- The System Operating Ranges such as the Operating Temperature, and Relative Humidity are the same for both the Subject Device and Predicate Device.
- The Mode of Operation and technological characteristics like the Maximum Field of View, Working length and Bending Section Angulation range is identical for both the Subject Device and Predicate Device.
- The Process Box Characteristics such as the Digital Output, Control Signals, Electrical Class and features such as the light Intensity Control and freeze/release are identical for both the Subject Device and Predicate Device.

5.6.3.2. Differences

- Characteristics such as the Voltage Operating Range, Depth of Field, Instrument channel Inner Diameter, Maximum Distal End Outer Diameter and Insertion Tube Outer Diameter are different for both the Subject Device and Predicate Device.

The differences between the Subject Device and the Predicate Device do not raise new questions of safety and efficacy. Testing conducted by Saneso demonstrates that the Subject Device performs as intended.

Saneso
Endoscopy Reinvented™

5.6.4. Saneso Single Camera Gastroscope-A, (Model: With and Without SBI) VS EVIS EXERA II GIF-H180

Table 4: Substantial Equivalence table for Saneso Single Camera Gastroscope-A (Model: With and Without SBI)

Parameter	Subject Device: Saneso Single Camera Gastroscope-A (Model: With and Without SBI)	Predicate Device: Evis Exera II GIF-H180	Equivalence
Manufacturer	Saneso, Inc.	Shirakawa Olympus Co., Ltd	-
Device Name	Saneso Single Camera Gastroscope-A	Evis Exera II GIF-H180	-
510(k) Number	-	K100584	-
Classification Product Code/Regulator Number	FDF 876.1500	FDF 876.1500	
Subsequent Product Code	FET, NWB	FDS	
Regulatory Class	II	II	**Equivalent**
Indications for Use	The Saneso Single Camera Gastroscope-A is intended for diagnostic visualization of the upper gastrointestinal tract (including the esophagus, stomach and duodenum). The system also provides access for therapeutic interventions using standard endoscopy tools. The Saneso system consists of Saneso Single Camera Gastroscope-A, Saneso Processor-A and other ancillary equipment.	The EVIS EXERA II GIF-H180 has been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy and other ancillary equipment for endoscopy and endoscopic surgery within the upper digestive tract (including the esophagus, stomach, and duodenum).	**Equivalent**
Colonoscope Type	Flexible	Flexible	**Equivalent**

OTC/Rx	Rx	Rx	Equivalent
System Operating Ranges			
Operating Temperature	10℃ - 40℃	10℃ - 40℃	**Equivalent**
Relative Humidity	85% maximum without condensation	30% - 85%	**Equivalent**
Operating Range	120V and 240V 60Hz	100V - 240 V(50/60 Hz)	**Equivalent**
Performance Characteristics			
Mode of Operation	The Processor relays video signals from the endoscope to a video monitor.	The Processor relays video signals from the endoscope to a video monitor.	**Equivalent**
Maximum Field of View	140°	140°	**Equivalent**
Depth of Field [mm]	2 - 100 mm	2 - 100 mm	**Equivalent**
Working Length	104 cm	103 cm	**Different**
Instrument channel Inner Diameter	3.7 mm	2.8 mm	**Different**
Maximum Distal End Outer Diameter	11.6 mm	9.8 mm	**Different**
Insertion Tube Outer Diameter	11.5 mm	9.8 mm	**Different**
Bending Section: Angulation Range	Up/Down: 180° Left/Right: 160°	Up: 210° Down: 90° Left/Right: 100°	**Different**
HD Technology	Yes	Yes	**Equivalent**
Processor Box Characteristics			
Digital Output (Display)	3 channels DVI	3 channels DVI	**Equivalent**
Control Signals	White balance A/W	White balance A/W pump	**Equivalent**

	pump control Light control	control Light control	
Electrical Class	Class I, Type BF	Class I, Type BF	**Equivalent**
Light Intensity Control	Yes	Yes	**Equivalent**
Enhancement Mechanism	Yes (White Light with Select Band Imaging)	Yes (White Light and Narrow Band Imaging)	**Equivalent with respect to Saneso Single Gastroscope with/without SBI**
Freeze/Release	Yes	Yes	**Equivalent**
CCD Type	Colour	Colour	**Equivalent**

5.6.4.1. Similarities

- The intended use is the same for the Subject Device and Predicate Device. Both devices belong to the same Regulatory class and both are prescription devices.
- The System Operating Ranges such as the Operating Temperature, and Relative Humidity are the same for both the Subject Device and Predicate Device.
- The Mode of Operation and technological characteristics such as the Maximum Field of View, is identical for both the Subject Device and Predicate Device.
- The Process Box Characteristics such as the Digital Output, Control Signals, Electrical Class and features such as the light Intensity Control and freeze/release are identical for both the Subject Device and Predicate Device.

5.6.4.2. Differences

- Characteristics such as the Voltage Operating Range,, Working length, Instrument channel Inner Diameter, Maximum Distal End Outer Diameter, Insertion Tube and Bending Section Angulation Range are different for both the Subject Device and Predicate Device.

The differences between the Subject Device and the Predicate Device do not raise new questions of safety and efficacy. Testing conducted by Saneso demonstrates that the Subject Device performs as intended.

5.7. Non-Clinical Study

Saneso-A Series (Saneso Colonoscope 360-A (With and Without SBI/DBI), Saneso Gastroscope 360-A (With and Without SBI/DBI), Saneso Single Camera Colonoscope-A (With and Without SBI), Saneso Single Camera Gastroscope-A (With and Without SBI))

The performance testing has been carried out in accordance with the FDA guidelines. The performance of the device was tested against the established System and Software Requirements to ensure that the device performs as intended. The Device Hazard analysis was completed and the risk controls were implemented to mitigate all the identified hazards. The testing results reflect that all the hardware specifications and software specifications have met the specified acceptance criteria. The performance testing demonstrates that Saneso-A series is safe and effective as the predicate device. The Saneso-A system complies with applicable standards for Electromagnetic Compatibility, Electrical Safety and Biocompatibility according to national and international standards. The following testing has been performed to demonstrate that the design outputs of the device meet the design input requirements. The tests were conducted either within Saneso, Inc.'s laboratory or by accredited third parties.

Table 5: List of Tests Performed - Saneso-A Series

Testing Type	Test Description	Test Result
Electrical Safety and Electromagnetic Compatibility Testing	- IEC 60601-1-2 - ANSI AAMI ES60601-1	The Saneso-A series met all acceptance criteria in accordance with IEC 60601-1-2, ANSI AAMI ES60601-1
Biocompatibility	- Cytotoxicity - Sensitization - Irritation	The Saneso-A series is biocompatible. Saneso, Inc., has performed biocompatibility testing for Saneso Endoscope 360-A, which has the same components and manufacturing processes as the Saneso Single Camera Endoscope-A. Also, Saneso, Inc., has provided a

		comparison table outlining the reprocessing steps performed prior to conducting the cytotoxicity study and the reprocessing steps outlined in the Reprocessing Manual which meets the worse case scenario for assessing biocompatibility. .
Cleanability	Cleaning Validation	The Saneso-A series met all the acceptance criteria and demonstrated that the cleaning process does not impact the functionality of the device.
High Level Disinfection	High Level Disinfection Report	The Saneso-A series met all the acceptance criteria and demonstrated that high level disinfection does not impact the functionality of the device.
Performance Bench Testing	Verification Reports	The Saneso-A series met all the design verification & validation, performance test requirements.

Software Verification and Validation Testing

Saneso-A Series (Saneso Colonoscope 360-A (With and Without SBI/DBI), Saneso Gastroscope 360-A (With and Without SBI/DBI), Saneso Single Camera Colonoscope-A (With and Without SBI), Saneso Single Camera Gastroscope-A (With and Without SBI))

Software Verification and Validation testing were conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device is considered as a '**moderate**' level of concern, since the software device is an accessory to a medical device that has a Moderate Level of Concern.

5.8. Clinical study

Saneso, Inc. has performed a prospective, multi-center clinical study to assess the successful intubation of the third portion of the duodenum, as per the protocol defined. The objective of the study can be described as the confirmation of procedural

performance of the Saneso 360-A gastroscope in Esophago-gastro-duodenoscopy (EGD) procedures. The study was performed on 22 subjects across 3 sites and consisted of subjects of both genders within the age range of 18 - 74 years, who were indicated for a routine EGD procedure. Pregnant women and subjects for whom routine endoscopic procedures are contraindicated due to comorbid medical conditions were excluded. The primary outcome of the study was successful completion of the EGD procedure. Procedure success is defined as by successful intubation of the third portion of the duodenum. Secondary outcomes of the study included qualitative rating by the endoscopists of the Saneso 360 gastroscope and the traditional gastroscope (Olympus GIF-H180 - K100584). Any potential mucosal injury resulting from use of the study device was evaluated using a scoring system of 1 - 5 immediately after the use of the device.

The Subject Device was comparable to the Predicate Device in terms of performance and safety. Procedural success rate of 100% was achieved with both Saneso and Olympus gastroscopes. The total procedure time and withdrawal time was significantly greater for the Saneso gastroscope ($p>0.5$ and $p<0.5$ respectively). No complications or evidence of mucosal injury were reported/observed with the use of Saneso gastroscopes.

Further, the Saneso gastroscope was rated superior to Olympus gastroscope in terms of the field of view by the endoscopists who performed the procedure. The Saneso gastroscope was rated substantially equivalent to Olympus GIF-H180 gastroscope in other visualization and mechanical characteristics.

The results of the study are documented in the clinical study report.

5.9. Conclusion

Saneso Colonoscope 360-A (Model: With and Without SBI/DBI)

Saneso Colonoscope 360-A is substantially equivalent to the Predicate Device, EVIS EXERA II Colonovideoscope CF-H180AL and Reference Device, Evis Exera 140 System PCF 140L in terms of technological characteristics, performance characteristics, system operating ranges and intended use. Performance testing demonstrates that Saneso Colonoscope 360-A is as safe and effective as the Predicate Device.

Saneso Gastroscope 360-A (Model: With and Without SBI/DBI)

Saneso Gastroscope 360-A is deemed substantially equivalent to the Predicate Device, Evis Exera II Gastrointestinal Videoscope GIF-H180 and Reference Device, Evis Exera 140 System GIF 140 in terms of technological characteristics, performance characteristics, system operating ranges and intended use. Performance testing demonstrates that Saneso Gastroscope 360-A is safe and effective as the Predicate

Device.

Saneso Single Camera Colonoscope-A (Model: With and Without SBI)

The Saneso Single Camera Colonoscope-A is deemed substantially equivalent to the Predicate Device Olympus PCF Q180AL in terms of technological characteristics, performance characteristics, system operating ranges and intended use. Performance testing demonstrates that Saneso Single Camera Gastroscope-A is safe and effective as the Predicate Device.

Saneso Single Camera Gastroscope-A (Model: With and Without SBI)

The Saneso Single Camera Gastroscope-A is deemed substantially equivalent to the Predicate Device, Evis Exera II GIF-H180 in terms of technological characteristics, performance characteristics, system operating ranges and intended use. Performance testing demonstrates that Saneso Single Camera Gastroscope-A is safe and effective as the Predicate Device.