February 27, 2023

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

Re: K222173
Trade/Device Name: Saneso Lens Wash Bottle Assembly (SAN-LWB-A)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCX
Dated: January 24, 2023
Received: January 24, 2023

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,

Sivakami Venkatachalam -S

for
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)*
K222173

Device Name
Saneso Lens Wash Bottle Assembly (SAN-LWB-A)

Indications for Use *(Describe)*
The Saneso Lens Wash Bottle Assembly (SAN-LWB-A) is intended to be used with FDA-cleared Saneso endoscopes.

It facilitates the following:

1. Sterile water for lens wash function
2. Air / CO2 for luminal insufflation function

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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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

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: 07/15/2022

5.2. Device Information

Common/Usual Name: Endoscope, Water Bottle with cap and tubing
Trade Name: Saneso Lens Wash Bottle Assembly (SAN-LWB-A)
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Classification Panel: Gastroenterology/Urology
Product Code: OCX
Regulation Number: 21 CFR Part 876.1500

5.3. Predicate Device Information

Saneso Lens Wash Bottle Assembly is substantially equivalent to the following cleared device:

Company	Predicate Device Priority	Product	510(k) Number
Saneso Inc.	Primary	Saneso - A series	K210052

5.4. Device Description

The Saneso Lens Wash Bottle Assembly is intended to be used with Saneso endoscopes.

It facilitates the following:

1. Sterile water for lens wash function
2. Air / CO2 for luminal insufflation function

Saneso lens wash & insufflation system is divided into proximal and distal sections:

Proximal Section: It comprises the Lens Wash Bottle Assembly and terminates at its

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connection with the air/water port on the endoscope. It consists of the lens wash bottle, lens wash bottle cap, airline, water line, CO2 line, and air/water connector. This section is the non-patient contacting portion of the system and is covered in this submission.

Distal Section: It starts at the air/water port and terminates at the air/water nozzles on the distal end of the endoscope. It consists of the air/water port, air/water valve, air/water channel, and the lens wash nozzles, which are all located in the endoscope. This section is the patient contacting portion of the system and is part of the Saneso endoscopes, which is FDA 510k approved (K210052).

5.5. Intended Use

5.5.1. Subject Device

The Saneso Lens Wash Bottle Assembly (SAN-LWB-A) is intended to be used with FDA-cleared Saneso endoscopes.

It facilitates the following:

- Sterile water for lens wash function
- Air / CO2 for luminal insufflation function

5.5.2. Primary Predicate Device

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 to 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.

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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 to therapeutic interventions using standard endoscopy tools. The Saneso system consists of Saneso Single Camera Gastroscope, Processor-A, and other ancillary equipment.

Note: The scope of the submission is not the endoscope (Colonoscope and the gastroscope) but the Lens wash bottle alone. Lens wash bottle is intended to be used only as an accessory to the endoscope system (SAN-A series) which was originally cleared by the FDA with K number K210052. There is no modification in the system, but there is a modification in the accessory where it is changing from single-use to multi-use, and it is supported by the reprocessing validation results.

5.6. Technological Characteristics

Table 1: Substantial Equivalence Table for Saneso Lens Wash Bottle Assembly

Parameter	Subject Device	Primary Predicate Device	Equivalence
510(k) Number	-	K210052	NA
Product code	OCX	FDS, FDF	Equivalent
Regulation No.	21 CFR Part 876.1500	21 CFR Part 876.1500	Equivalent
Classification:	Class II	Class II	Equivalent
Regulation Name	Endoscope and Accessories	Endoscope and Accessories	Equivalent
Prescription Use/OTC	Prescription Use	Prescription Use	Equivalent
Intended Use	The Saneso Lens Wash Bottle Assembly is intended to be used with the FDA cleared Saneso endoscopes. It facilitates the following: a. Sterile water for lens wash function b. Air / CO2 for	**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	Equivalent **Note:** The scope of the submission is not the endoscope (Colonoscope and the gastroscope) but the Lens wash bottle alone.

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	luminal insufflation function	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	Lens wash bottle is intended to be used only as an accessory to the endoscope system (SAN-A series) which was originally cleared by the FDA with K number K210052. There is no modification in the system, but there is a modification in the accessory where it is changing from single-use to multi-use, and it is supported by the reprocessing validation results.

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		access for therapeutic interventions using standard endoscopy tools. The Saneso system consists of Saneso Single Camera Colonoscope, Processor-A and other ancillary equipment. **<u>Saneso Gastroscope 360- A</u>** 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.	
Construction/Components	The Saneso Lens Wash Bottle Assembly consists of a reusable lens wash water bottle (cylindrical bottle), cap, tubing set and air/water connector.	The Saneso Lens Wash Bottle consists of a single-use lens wash water bottle (cylindrical bottle), cap, tubing set and air/water connector.	Equivalent
Sterile/Non Sterile	Sold Non - Sterile	Sold Non - Sterile	Equivalent
Accessories	• Cap CO2 outlet • Water line • Cap water outlet	• Cap CO2 outlet • Water line • Cap water outlet • CO2 line	Equivalent

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	• CO2 line • Air Line • CO2 clamp • Cap Air inlet	• Air Line • CO2 clamp • Cap Air inlet	
Usage	Reusable	Single Use	Different
Method of Application	Manual	Manual	Equivalent
Compatible Endoscopes/processors	Saneso - A series (K210052), Saneso Processor - A	Saneso - A series (K210052), Saneso Processor - A	Equivalent

5.6.1. Similarities

The Saneso Lens Wash Bottle Assembly SAN-LWB-A is similar to the Lens Wash Bottle which is cleared under K210052 in terms of intended use, construction/components, method of application.

5.6.2. Differences

The difference between the Saneso Lens Wash Bottle Assembly SAN-LWB-A and the Lens Wash Bottle which is cleared under K210052 is its usage, ie; from single use to multi-use. However, this difference does not raise new questions of safety or efficacy. Differences were justified using Non-Clinical performance testing - Manual Cleaning Validation and Steam Sterilization Validation and demonstrates that the Lens wash bottle Assembly is safe and effective.

5.7. Summary of Non-Clinical Tests

Performance testing was performed as per the relevant standards and test procedures listed in the Declaration of Conformity.

1. Manual Cleaning Validation - Cleaning validation was performed using Saneso's recommended cleaning procedure. Saneso Lens Wash Bottle Assembly met all the acceptance criteria and demonstrated that the cleaning process does not impact the functionality of the device.

2. Steam Sterilization Validation - Sterilization validation was performed and Saneso Lens Wash Bottle Assembly met all the acceptance criteria. The device is found to be safe and effective.

5.8. Summary of Clinical Tests

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5.8.1. Animal Study

No animal studies have been conducted for the Subject Device.

5.8.2. Clinical Study

No clinical studies have been conducted for the Subject Device.

5.9. Conclusion

Saneso Lens Wash Bottle Assembly SAN-LWB-A is substantially equivalent to the Lens Wash Bottle which is cleared under K210052 in terms of intended use and technological characteristics. Differences were justified using Non-Clinical performance testing. Thus, Saneso Inc. has concluded that the device does not introduce any significant questions of safety and efficacy and is substantially equivalent.