November 30, 2023

SurgEase Innovations Limited
Roger Parker
Head of Hardware Engineering
Pendle Innovation Centre, Brook Street
Nelson
Lancashire, BB9 9PU
United Kingdom

Re: K232262
Trade/Device Name: LumenEye® X1 endoscope (LX1-SCP-203); LumenEye® X1 consumables (LX1-CSB-201); LumenEye® X1 Consumable Carton (25 Sets) (LX1-CSP-201)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FAN
Dated: October 10, 2023
Received: October 16, 2023

Dear Roger Parker:

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,

Shanil P. Haugen -S

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.

Submission Number *(if known)*

K232262

Device Name

LumenEye® X1 endoscope (LX1-SCP-203);
LumenEye® X1 consumables (LX1-CSB-201);
LumenEye® X1 Consumable Carton (25 Sets) (LX1-CSP-201)

Indications for Use *(Describe)*

The LumenEye® X1 device is intended to be used to examine the rectum, and using additional accessories, perform tissue sampling of the rectum, if required.

The LumenEye® X1 can enable suitably trained healthcare professionals in clinical environments, when used in conjunction with other tests, to examine the rectum as part of a clinical assessment in adults.

The LumenEye® X1 is not intended to determine a final clinical diagnosis without further confirmatory tests. Following examination, the healthcare practitioner may make recommendations for further investigations as appropriate.

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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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92. All data included in this document is accurate and complete to the best of SurgEase Innovations' knowledge.

1. Device Details

Applicant: SurgEase Innovations Ltd.
Pendle Innovation Centre
Brook Street, Nelson
Lancashire, UK
BB9 9PU

Contact: Roger Parker
Head of Hardware
Email: roger.parker@surgease.co.uk
Mobile: +44 (0) 7793054510

Date Prepared: 2023-Jul-31

Common Name: Rectoscope (Rigid)

Trade names: LumenEye® X1 Endoscope
LumenEye® X1 Consumable Pack
LumenEye® X1 Consumable Carton (25 Sets)

Model Number: LumenEye® X1 Endoscope: LX1-SCP-203
LumenEye® X1 Consumable Pack: LX1-CSB-201
LumenEye® X1 Consumable Carton (25 Sets): LX1-CSP-201

Regulation Number: 21 CFR Part 876.1500
Regulation Name: Endoscopes and Accessories
Regulatory Class: Class II

Product Code: FAN – Sigmoidoscope, electric, rigid.
Medical Speciality: Gastroenterology/Urology

Predicate Device: SIGMOIDOSCOPE, DISPOSABLE, MODEL #53125
Manufacturer: Welch Allyn, Inc., United States
510(K) Number: K770291

Reference device: PENTAX Medical VIVIDEO ENT Videoscope Solution, VNL9-CP
Manufacturer: Pentax Medical
510(K) Number: K171011

2. Device Description

The LumenEye® X1 is a re-usable handheld rigid endoscope that permits insufflation of the rectum and endoluminal high-definition video capture to enable an examination of the rectum (Figure 1). The device has no lumens or channels within the reusable elements of the handle.

Figure 1 | Image of device assembled with sheath and obturator attached.

The area of interest is illuminated by a distally mounted ring of LEDs which emit white light (5300K). Light reflected from the subject is captured by the HD CMOS sensor. The LEDs and camera sensor are housed in the distal end of a stainless-steel camera tube. The image is transferred via USB protocol to a PC and displayed on a screen. There is limited firmware capability within the sensor which simply enables the LEDs to turn on when a video feed from the camera is requested by the PC. The device functions with any Off-the-shelf (OTS) software with a camera display capability. The full HD CMOS camera provides 1080p, 90° field of view and a frame rate of 60 frames per second. The camera enclosure is IP67 rated.

The device features a 1.8m long PVC cable and is powered via USB 3.0 Type-A connection (maximum input voltage 5V, rated current 500mA).

3. Indications for Use

The LumenEye® X1 device is intended to be used to examine the rectum, and using additional accessories, perform tissue sampling of the rectum, if required.

The LumenEye® X1 can enable suitably trained healthcare professionals in clinical environments, when used in conjunction with other tests, to examine the rectum as part of a clinical assessment in adults.

The LumenEye® X1 is not intended to determine a final clinical diagnosis without further confirmatory tests. Following examination, the healthcare practitioner may make recommendations for further investigations as appropriate.

4. Summary of Technological Characteristics

The LumenEye® X1 is substantially equivalent to the predicate device. The subject and predicate share the same intended use and the indicated patient population and anatomical site for the subject device are also identical. However, there are some differences in technological characteristics, as summarised in Table 1.

The major difference between the subject device and predicate device is that the LumenEye® X1 is a device with a HD camera allowing HD digital visualisation of the rectum, whereas the predicate provides a method for direct viewing of the rectum via a proximally placed viewing window. Owing to the differences between the subject and predicate device (i.e. analogue versus digital visualisation), a reference device with a similar technological profile was selected (PENTAX Medical VIVIDEO ENT Videoscope Solution, Model VNL9-CP). The technical (optical) specifications of the chosen reference device closely match those of the subject device.

While there are some differences in the dimensional specifications in the subject device, these differences have been evaluated through performance testing and raise no issue of

safety and effectiveness of the subject device as these differences have no effect on the performance, function or general intended use of the device.

	Subject Device	**Predicate Device**	**Reference Device**
Indications For Use	Used to examine the rectum, and using additional accessories, perform tissue sampling of the rectum, if required.	Used to examine the rectum and lower bowel, and using additional accessories, perform various diagnostic and/or therapeutic procedures.	N/A
Reusable	Yes	Yes	N/A
Reprocessing	Manual cleaning Sterilisation (V-PRO maX 2)[1]	Manual cleaning Intermediate Level Disinfection	N/A
Power Source	5V (USB-A connection to PC/Laptop)	3.5V (Battery)	N/A
Material	Endoscope Handle: PC+ABS Sheath and Obturator: Polypropylene Endoscope Camera Stalk: SS 316L	Sigmoidoscope Handle: Stainless Steel Obturator: Plastic	N/A

	Subject Device	**Predicate Device**	**Reference Device**
Insufflation	Insufflation Bulb (integrated) Single use filter	Insufflation Bulb (separate) Single use filter	N/A
Diameter (Sheath)	19mm	19mm	N/A
Length (Sheath)	20cm	25cm	N/A
Integrated LED	Yes (tip)	No (Halogen light)	Yes (tip)
Imaging Technology	White Light Imaging	N/A	White Light Imaging
Depth of Field	40mm	N/A	5-50mm
Field of View	90°	N/A	90°
MTF50	0.12 (@40mm) [cycle/mm]	N/A	3.58 (@30mm) [cycle/mm]

Table 1 | Comparison table of technological characteristics between subject, predicate and reference devices.
Note 1: Recommended by the FDA

5. Non-Clinical Performance Data

The LumenEye® X1 has been successfully tested for its functions, performance and safety as per FDA recognized consensus standards. Testing has been conducted as per IEC60601-1, IEC 60601-1-2, IEC 62471, and ISO 10993. Risk analysis was carried out in accordance with ISO 14971:2019. Design verifications tests and acceptance criteria were defined and performed as a result of this risk analysis assessment. Verification bench testing of the LumenEye® X1 was performed including operational and functional testing, to ensure that the subject device meets the design specifications and performs as intended. These following performance data provided in support of the substantial equivalence determination.

Optical Testing

Optical properties including signal to noise ratio, spatial resolution (Modulation Transfer Function, MTF), distortion, light distribution, and spectral distribution were measured for the Lumen Eye X1's HD CMOS camera. All results show that there are no differences between the subject and the reference device.

Reprocessing Validation

Simulated use testing, pre-cleaning, cleaning, rinsing and sterilization validation studies of the Lumen Eye X1 were conducted and confirmed the effectiveness of reprocessing procedures in accordance with FDA's 2015 Final Guidance, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling ("FDA's 2015 Reprocessing Guidance") and ISO 17664:2017. Acceptance criteria were established in accordance with AAMI TIR 30:2011 for amount of residual soil accumulation and extraction efficiency. Acceptance criteria were met after each phase of reprocessing. Note that sterilization is performed using the V-PRO maX 2 method and replaces high level disinfection as the Lumen Eye X1 endoscope cannot be fully immersed in liquid.

Sterilization and Shelf Life

Shelf-life is not applicable to the subject device and consumables as they are not provided sterile as they are indicated for use in an anatomical region inherently contaminated (high burden of microbes), and therefore the risk of harm is negligible. Furthermore, the predicate device is not provided sterile. Additionally, shelf-life is not applicable to the subject device and consumables because the materials do not degrade significantly over time (i.e. performance is unaffected).

Biocompatibility

Biocompatibility of direct and indirect contact materials was confirmed by assessing the cytotoxicity, sensitization and intracutaneous reactivity of the surface device with limited

(less than 24 hours) contact with mucosal membrane in accordance with ISO 10993-1, 5, and 10: Biological Evaluation of Medical Devices.

Software

Software verification and validation testing were conducted and documentation was provided 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 level of concern is "Moderate".

Cybersecurity risks have been assessed and mitigated according to the FDA Guidance for Industry and Staff "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices."

EMC and Electrical Safety

The acceptable level of electromagnetic compatibility (EMC) and electrical safety (ES) for the Lumen Eye X1 were confirmed by the following standards:

- IEC 60601-1 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AMD1 (2012)
- IEC 60601-1-2:2014 (4th Edition)
- IEC 60601-2-18:2009

6. Substantial Equivalence Discussion

After analysing the intended use, indications for use, technological characteristics (including fundamental operating principle, energy source, scientific technology, functional characteristics, design features, performance characteristics, and constituent materials), labelling, and sterilization method, we conclude that the subject device is as safe and effective as the predicate device. The differences in indications and intended use between the subject and predicate devices, do not raise new concerns of safety and effectiveness and are therefore, substantially equivalent. The technological differences in terms of design features, performance characteristics and constituent materials are not substantive.

7. Conclusion

It can be concluded that the LumenEye X1® is substantially equivalent to the predicate Welch Allyn disposable sigmoidoscope with respect to the intended use, principles of operation and technical characteristics.