



October 9, 2025

Haemoband Surgical LTD
Cathal Donnelly
Operations Executive
The Mount Business Centre
2 Woodstock Link
Belfast, BT68DD
United Kingdom

Re: K250645

Trade/Device Name: SleeveLUX 24 Anoscope/Proctoscope (P2001); SleeveLUX 16
Anoscope/Proctoscope (P2002)

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope And Accessories

Regulatory Class: Class II

Product Code: FER, GCP

Dated: April 2, 2025

Received: September 10, 2025

Dear Cathal Donnelly:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,

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

Indications for Use

Submission Number (if known)

K250645

Device Name

SleeveLUX 24 Anoscope/Proctoscope (P2001);
SleeveLUX 16 Anoscope/Proctoscope (P2002)

Indications for Use (Describe)

SleeveLUX Anoscope/Proctoscope is a class 2 self-illuminating disposable instrument used to assist clinicians when treating and/or diagnose conditions in the anal canal and the lower rectum such as 1st 2nd and 3rd degree hemorrhoids.

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

Prepared on: 2025-09-10

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Haemoband Surgical LTD
Applicant Address	The Mount Business Centre 2 Woodstock Link Belfast BT68DD United Kingdom
Applicant Contact Telephone	028 9073 7283
Applicant Contact	Mr. Cathal Donnelly
Applicant Contact Email	cdonnelly@haemobandsurgical.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	SleeveLUX 24 Anoscope/Proctoscope (P2001); SleeveLUX 16 Anoscope/Proctoscope (P2002)
Common Name	Endoscope and accessories
Classification Name	Anoscope And Accessories
Regulation Number	876.1500
Product Code(s)	FER, GCP

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K070913	Self-light disposable anoscope/proctoscope	FER

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The SleeveLUX Anoscope/Proctoscopes (PS24000001) are class 2 self-illuminating, single use, disposable instrument (medical device) used to assist clinicians treat and/or diagnose conditions in the anal canal and the lower rectum such as 1st 2nd and 3rd degree hemorrhoids. The SleeveLUX Anoscope/Proctoscopes must only be used by trained professionals. The SleeveLUX Anoscope/Proctoscope is not manufactured using tissues of animal origin, does not contain human blood derivatives or medicinal products.

The SleeveLUX Anoscope/Proctoscope is a plastic self-illuminating disposable instrument comprised of five main components:

- Main body tube
- Sleeve
- Trocar
- Handle
- LED module

The SleeveLUX is used for diagnosing and treating conditions in the lower rectum and anal canal. The trocar and sleeve are introduced to position the sleeve in the anus. After the trocar is removed, the main body tube is then inserted into the anus aligning the locking system on the sleeve and main body tube. The LED module can then be switched on. The SleeveLUX can then freely move within the sleeve with no discomfort to the patient eliminating the need for multiple introductions. The locking system also helps prevent withdrawing a biopsy or treating hemorrhoids distal to the dentate line.

Proctoscopy is a common procedure performed to examine the anal canal and rectum for conditions such as anal fissures haemorrhoids, carcinoma, inflammation, internal bleeding, tumours and polyps. A proctoscope is a very general and novel tool that can also be used therapeutically in conduction with other instruments such as band ligators, forceps catheters and other general surgical equipment for

the treatment of haemorrhoids, polypectomy and to take biopsies. The forementioned conditions usually occur the adult population (+18) and affect both genders, therefore the target population is widespread and general to adults. The proctoscope/anoscope should be used with caution when treating a patient on anticoagulants.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

SleeveLUX Anoscope/Proctoscope is a class 2 self-illuminating disposable instrument used to assist clinicians when treating and/or diagnose conditions in the anal canal and the lower rectum such as 1st 2nd and 3rd degree hemorrhoids.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use are effectively the same for both devices, as the devices are intended to be use in the examination of the lower rectal region.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The predicate device and the device being submitted, as composed of the same material (Polycarbonate), the devices are both used in the examination of the anal canal, both have integrated light sources. Both have the same intended use and both require a trained professional to operate. Similar shelf lives of 5 years (predicate) and 3 years(Submitting device)

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Mechanical testing was completed on the device to ensure the mechanical properties of the device are suitable for its intended purpose.

No clinical testing preformed.

From the information gathered in the non clinical and mechanical testing completed on the device, we can conclude that there is no issues raised regarding the cytotoxicity, irritation or sensitization of the device and that the device has the mechanical proprieties to achieve its intended use.