April 28, 2025

Contra Healthcare Solutions, LLC
John O'Connor
President
105 Lincoln Avenue
Butler, Pennsylvania 16001

Re: K243532
Trade/Device Name: LumiRex Ureteroscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Received: March 31, 2025

Dear John O'Connor:

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,

Mark J. Antonino -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K243532

Please provide the device trade name(s).

LumiRex Ureteroscope

Please provide your Indications for Use below.

The LumiRex Single-Use Digital Flexible Ureteroscope is a single-use video endoscope designed for use with Contra Healthcare Solutions video processors, urology accessories, and other ancillary equipment used in urology and urological procedures.

Please select the types of uses (select one or both, as applicable).

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

510(k) #: K243532

510(k) Summary

Prepared on: 2025-04-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Contra Healthcare Solutions, LLC
Applicant Address	105 Lincoln Avenue Butler PA 16001 United States
Applicant Contact Telephone	724-285-6324
Applicant Contact	Mr. John O'Conner
Applicant Contact Email	joconnor@alpinsurgical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	LumiRex Ureteroscope
Common Name	Ureteroscope
Classification Name	Endoscope and accessories
Regulation Number	876.1500
Product Code(s)	FGB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K172098	Pusen Medical Video Endoscope System	FGB

Device Description Summary

21 CFR 807.92(a)(4)

The LumiRex Single-Use Ureteroscope is a flexible video-based medical device designed for insertion through the urethra into the urinary tract. It comprises a long, thin tube equipped with a light source and a camera to provide real-time visualization of the urinary tract and interior of the kidney. The ureteroscope also features a working channel that allows for installation of fluids, the passage of various instruments, such as biopsy forceps, cytology brushes, biopsy brushes, and stone retrieval baskets to facilitate urology and ureteroscopy procedures.

The ureteroscope can be used wired or wireless through a Wireless Scope Adapter or Wired Scope Adapter. The adapters transmit images from the ureteroscope to the Video Processor Unit where the user can view the image from the ureteroscope, control the LED, and save and export images from the ureteroscope onto USB removable media.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The LumiRex Single-Use Digital Flexible Ureteroscope is a single-use video endoscope designed for use with Contra Healthcare Solutions video processors, urology accessories, and other ancillary equipment used in urology and urological procedures.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device LumiRex Ureteroscope has the same indications for use as the predicate device Pusen Medical Video Endoscope system (K172098).

Technological Comparison

21 CFR 807.92(a)(6)

Overview of Similarities

The subject device and the predicate device have the same basic form factor, digital video and illumination sources, and are both single-use. Both devices utilize a video processing unit to view and control the image displayed to the user.

Overview of Differences

The subject device allows the user to operate the device wirelessly and wired through respective adapters while the predicate device only has the option of wired use. The LumiRex Ureteroscope when used with the Wired Scope Adapter of the subject device is operated in the same manner as the predicate device. The Wireless Scope Adapter of the subject device has a built-in battery powering the ureteroscope and allows better maneuverability and convenience during use for healthcare providers. The risks of wireless use have been assessed and found to be acceptable. The functionality of the ureteroscope with wireless adapter has been validated.

The subject device video processing unit can be powered by the mains or lithium battery, while the predicate device's video processing unit is powered only by mains.

Comparative testing between the subject device and predicate device showed that the subject device has a wider field of view but same depth of view.

The above differences between the subject and predicate device do not raise different questions of safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical validation testing was performed to demonstrate the safety and effectiveness of the device. The following tests were performed:

Sterilization and Shelf-Life
Ethelyne Oxide Sterilization of LumiRex Single-Use Bronchoscope has been evaluated to ISO 11135:2014. Sterile Barrier was evaluated to ISO 11607-2:2019 and ASTM F1980 for accelerated aging methodology. The shelf life of the LumiRex Single-Use Bronchoscope has validated.

Reprocessing
Reprocessing of reusable components of the LumiRex Single-Use Bronchoscope has been evaluated in accordance with:
• Guidance for Industry and FDA Staff – Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling issued March 17, 2025
• AAMI TIR12:2020 Designing, testing, and labeling reusable medical devices for reprocessing health care facilities: A guide for medical device manufacturers
• AAMI/ANSI/ISO 11737-1:2018 Sterilization of health care products-Microbiological Methods Part 1: Determination of the Population Microorganisms on produce
• ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
• ANSI/AAMI/ISO 17665-1:2006/(R)2013 Sterilization of health care products – Moist heat – Part 1 Requirements for the development, validation, and routine control of a sterilization process for medical devices
• AAMI ST98:2022 Cleaning validation of health care products- Requirements for development and validation of a cleaning process for medical devices

Biocompatibility
The biocompatibility evaluation for the LumiRex device was conducted in accordance with the FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical device – Part 1: Evaluation and testing within a risk management process" issued September 4, 2020, and International Standard 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," FDA recognition number 258 for:
- Cytotoxicity (10993-5:2009)
- Sensitization (10993-10:2021)
- Systemic Toxicity (10993-11:2017)
- Pyrogenicity (10993-11:2017)
- Irritation (10993-23:2021)

Software
Software verification and validation testing has been conducted in compliance with IEC 62304 Edition 1.1 2015-06 (which is the principal normative standard applied), ANSI/AAMI/IEC ES60601-1:2005/(R)2012 and A1:2012 and the FDA guidance documents "General Principles of Software Validation; Final Guidance for Industry and FDA Staff" (11-Jan-2002) and "FDA Guidance for the Content of Premarket Submissions for Device Software Functions" (14-June-2023).

Cybersecurity
The cybersecurity of LumiRex Bronchoscope system was evaluated in conformance to "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" issued September 2023.

Electrical Safety and Electromagnetic Compatibility
The LumiRex Single-Use Bronchoscope, Wired Scope Adapter, Wireless Scope Adapter, Wireless Scope Adapter Charging Cradle, and LumiRex Video Processor have undergone the following Electrical Safety and Electromagnetic Compatibility testing, complying with IEC 60601-1:2005/IEC 60601-1-2:2014+A1:2020/AMD2:2020, IEC 60601-1-2:2014+A1:2020, and IEC 60601-2-18 (3rd edition).

Bench Testing
- ISO 80369-7:2021 Small-bore Connectors for Liquids and Gases in Healthcare Applications
- ISO 8600-1:2015 Endoscopes – General Requirements
- ISO 8600-3:2019 Endoscopes – Determination of field of view and direction of view of endoscopes with optics
- ISO 8600-4:2014 Endoscopes – Determination of maximum width of insertion portion
- IEC 62471:2006 Photobiological Safety
- Camera Image Quality
  - o Spatial Resolution MTF (ISO 12233)
  - o Signal to noise Ratio (ISO 15739)
  - o Dynamic Range
  - o Depth of Field
  - o Geometric Distortion
  - o Image Intensity Uniformity
  - o Color performance
- System Functional Testing
- Performance characteristics such as leaking, irrigation, bending, articulating bending angle, endurance of bending section, instrument and accessory compatibility, and bending section radius

Verification in Differences of Design
Scope Adapter – Evaluation of the LumiRex Bronchoscope for Reprocessing, Software, Electrical Safety, Electromagnetic Compatibility, and System Functional Testing, FDA Guidance Document - Electromagnetic Compatibility (EMC) of Medical Devices (June 6, 2022) – Section J – Common Electromagnetic (EM) Emitters, and IEEE/ANSI C63.27-2021 demonstrated that the device in design of the subject device in use wired/wireless scope adapters met requirements in the referenced standards and/or matched the performance of the predicate device. The results met the requirements defined in the standard and/or matched the performance of the predicate device.
Insertion Tube – To verify the design of the maneuverable portion, performance characteristic testing and testing per ISO 8600-1:2015 was performed. The bending performance of the LumiRex Bronchoscope met the requirements defined in the standard.
Image and Optical Characteristics - To verify the image and optical performance of the LumiRex Bronchoscope, comparative testing was performed between the predicate and subject device for Camera Image Quality, and Determination of Field of View and Direction of View (ISO 8600-3:2019). The results met the requirements defined in the standard and demonstrated substantially equivalent performance to the predicate device.