July 31, 2023

CenterPoint Systems, LLC
Marybeth Gamber
VP, Regulatory & Quality
3338 Parkway Blvd.
West Valley City, UT 84119

Re: K223097
Trade/Device Name: RenaNav Ureteroscope System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FGB
Dated: June 29, 2023
Received: June 30, 2023

Dear Marybeth Gamber:

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,

Mark R. Kreitz -S

for 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

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)*
K223097

Device Name
RenaNav Ureteroscope System

Indications for Use *(Describe)*
The ureteroscope is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

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.

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5 510(K) SUMMARY

5.1 Submitter

Name	CenterPoint Systems LLC
Address	3338 Parkway Blvd West Valley City UT
Phone	877-848-0828
Contact Person:	Marybeth Gamber, Vice President Regulatory Affairs & Quality Assurance
Date Prepared:	July 25, 2023

5.2 Device

Name of Device:	RenaNav Ureteroscope System
Common or Usual Name	Ureteroscope System
Regulation Name:	Endoscope and Accessories
Regulatory Class:	Class II per 21 CFR 876.1500
Product Code:	FGB

5.3 Predicate Device

Predicate Name and 510(k) Number: LithoVue System, K153049

This predicate has not been subject to a design-related recall.

No reference predicates were used in this submission.

5.4 Device Description

The RenaNav Ureteroscope System is comprised of a single-use ureteroscope and a multi-use video processing unit (VPU). The RenaNav Single-Use Digital Flexible Ureteroscope is a sterile, single use device and is compatible with the multi-use System Video Processing Unit. The Ureteroscope is used by physicians to access, visualize, and perform procedures in the urinary tract.

The flexible shaft of the ureteroscope includes one working channel which enables the delivery of therapeutic accessories and irrigation/ contrast solutions to the distal tip and desired anatomical location.

5.5 Indications for Use

The ureteroscope is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

The indications for use statement is identical to the predicate device.

5.6 Comparison of Technological Characteristics with the Predicate Device

The Proposed Device and Predicate Device are similar in indications for use, intended use, technological characteristics, and principles of operation.

The differences between the Proposed Device and the Predicate Device are minor and raise no different questions of safety and effectiveness, thus it was concluded that the Proposed Device is substantially equivalent to the Predicate Device. In accordance with 21CFR807.92(a)(6) a summary of how the technological characteristics of the Proposed Device compares to the Predicate Device is provided below.

Feature	RenaNav Single Use Digital Flexible Ureteroscope (proposed device)	Primary Predicate: LithoVue Single Use Digital Flexible Ureteroscope (K153049)	Same/Different between Proposed & Predicate
Intended Use/Indications for Use	The ureteroscope is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.	The ureteroscope is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.	Same
Device Class	II	II	Same
Product Code	FGB	FGB	Same
Regulation number	21 CFR 876.1500	21 CFR 876.1500	Same
Duration of use	Single-use, Transient	Single-use, Transient	Same
Insertion Site	Urethra or Percutaneous Access	Urethra or Percutaneous Access	Same
Sterilization	Ethylene Oxide	Ethylene Oxide	Same
Prescription Device	Yes	Yes	Same
Working Channel	3.6F	3.6F	Same
Working Length	68cm	68cm	Same

Feature	RenaNav Single Use Digital Flexible Ureteroscope (proposed device)	Primary Predicate: LithoVue Single Use Digital Flexible Ureteroscope (K153049)	Same/Different between Proposed & Predicate
Brightness Control	Yes	Yes	Same
Illumination Type	LED	LED	Same
Up/Down Deflection	270 degrees, both directions	270 degrees, both directions	Same
Guidewire Compatibility	Max outside diameter 0.97mm (0.038")	Max outside diameter 0.97mm (0.038")	Same
Minimum Bend Radius	8mm	8mm	Same
Materials/ Biocompatibility	Standard medical device materials The biocompatibility tests demonstrate that there are no adverse biocompatibility risks associated with use of this material. All test results met the requirements of ISO 10993-1.	Standard medical device materials. The biocompatibility tests demonstrate that there are no adverse biocompatibility risks associated with use of this material. All test results met the requirements of ISO 10993-1.	Same
Features	Handle, Articulation Lever, Umbilical Cable, Accessory Access Port, Irrigation Port	Handle, Articulation Lever, Umbilical Cable, Accessory Access Port, Irrigation Port	Same
EMC Safety Testing	Complies with applicable clauses of IEC-60601	Complies with applicable clauses of IEC-60601	Same

The RenaNav Ureteroscope System is used for the same intended use in the same anatomical location using the same principles of operation as the predicate device. Therefore, the RenaNav Ureteroscope System can be considered substantially equivalent to the predicate device.

5.7 Performance Data

All necessary performance testing has been conducted on the RenaNav Ureteroscope System to assure substantial equivalence to the predicate devices and to demonstrate the device performs as intended. All testing was performed on test units representative of finished devices. The device passed the following tests:

- Biocompatibility testing per FDA Final Guidance Document, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" (2020)
- Sterilization validation per ANSI/AAMI/ISO 11135
- Packaging validation per ANSI/AAMI/ISO 11607-1
- Electrical Safety and electromagnetic (EMC) Testing per applicable requirements of IEC 60601-1, IEC 60601-1-2, & IEC 60601-2-18.
- Simulated use testing, including use with ancillary devices

- Scope and VPU Dimensional verification, including proximal/distal OD, working length & ID, working channel length, curl diameter, umbilical cable length
- Deflection verifications
- Image testing, including illumination verification, Field of View and direction measurement, camera function, camera light ingress and glare
- HDMI compatibility
- Image functionality and gain function
- Sheath compatibility
- Leak test
- Tensile tests
- Optics testing, including Resolution, Depth of Field, Field of View, Geometric distortion, Signal-to-Noise Ratio, Dynamic Range, Image intensity uniformity, color performance.

5.8 Conclusions

Upon reviewing the information provided in this submission and comparing the intended use, principle of operation and overall technological characteristics, the RenaNav Ureteroscope System is substantially equivalent to existing legally marketed devices.