March 24, 2026

Carbon Medical Technologies, Inc.
Jared Klein
Manager, Regulatory Affairs
1290 Hammond Rd.
St, Paul, Minnesota 55110

Re: K253598
Trade/Device Name: InjecSURE Injection System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FBK
Dated: March 5, 2026
Received: March 5, 2026

Dear Jared Klein:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.	K253598

Please provide the device trade name(s).

InjecSURE Injection System

Please provide your Indications for Use below.

The InjecSURE® Injection System is intended for use as an accessory to currently marketed cystoscopes to allow delivery of injectable materials into urethral tissues of the lower urinary tract during cystoscopic 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) Summary – InjecSURE® Injection System

1. Submitter's Name, Address and Date of Submission

Jared Klein
Manager, Regulatory Affairs
Carbon Medical Technologies, Inc.
1290 Hammond Road
Saint Paul, MN 55110
Phone: 651-653-8512
Fax: 651-407-1975

Submitted: March 23, 2026

2. Device Name

Trade Name:	InjecSURE® Injection System
Common Name:	Injection Needle
Classification Panel:	Gastroenterology-Urology
Classification Name:	Endoscope And Accessories, 21 CFR 876.1500
Product Code:	FBK
Device Class:	Class II

3. Predicate Device(s)

The Carbon Medical Technologies, Inc. InjecSURE Injection System's legally marketed predicate device is the Repris Bladder Injection System, manufactured by URO-1, Inc.

Predicate Device: Repris Bladder Injection System (K180214)
This predicate device has not been subject to a design-related recall.

4. Reference Device(s)

The legally marketed devices identified in Table 1 were used as reference devices to support specific aspects of non-clinical performance testing and are not relied upon as predicate devices for purposes of substantial equivalence.

Table 1. Reference Device(s)

Reference Device	Manufacturer	510(k)	Product Code
USA Elite System Accessory Working Element (EAWE)	CIRCON ACMI	K890328	HIH
Injection Needle	Advanced Uroscience	K982890	FBK
LiNA OperaScope™	LiNA Medical	K193007	HIH / FAJ

None of the identified reference devices have been subject to a design-related recall.

5. Indications for Use

The InjecSURE® Injection System is intended for use as an accessory to currently marketed cystoscopes to allow delivery of injectable materials into urethral tissues of the lower urinary tract during cystoscopic procedures.

6. Device Description

The InjecSURE Injection System includes sterile, single-use components designed for one patient, featuring a 20 Ga, 5-inch (127 mm) needle—available with either a pencil-point or spinal tip—and a disposable sheath. The disposable sheath is compatible with 2.7 mm cystoscopes of various lengths.

The sheath attaches to a cystoscope to provide a guided pathway for the needle to reach the desired location.

7. Comparison of Technological Characteristics

The InjecSURE Injection System [subject device] is substantially equivalent (SE) to the URO-1 Repris Bladder Injection System [predicate device] as they share the same intended use and fundamental principles of operation.

Both devices function as cystoscopic injection accessories intended to deliver legally marketed injectable materials into tissue structures of the lower urinary tract under direct visualization. Each device consists of an introducer (sheath), injection needle, fluid ports, and luer connection interfaces, and is advanced in tandem with a cystoscope.

The table below compares the InjecSURE Injection System [subject device] to the Repris Bladder Injection System [predicate device] with respect to indications for use, intended use, principles of operation, device components, performance characteristics, sterilization modality, duration of use, and patient-contacting materials.

Although certain technological differences exist, including needle gauge, introducer dimensions, working length, sterilization modality, and specific anatomical site within the lower urinary tract, these differences do not alter the intended use or fundamental principles of operation. The technological differences can be evaluated through performance testing and do not raise new questions of safety or effectiveness.

Therefore, the InjecSURE Injection System is substantially equivalent to the cited predicate device. The Substantial Equivalence Comparison is presented in Table 2.

Table 2. Substantial Equivalence Comparison.

Characteristic	Subject Device	Predicate Device
Device Name	**InjecSURE Injection System**	**Repris Bladder Injection System**
Manufacturer:	Carbon Medical Technologies, Inc.	URO-1, Inc.
510(k) Number:	K253598	K180214
Indications for Use:	As an accessory to currently marketed cystoscopes to allow delivery of injectable materials into urethral tissues of the lower urinary tract during cystoscopic procedures.	Injection of drugs to address abnormal physiology in the lower urinary tract of adults.
Intended Use:	To deliver legally marketed injectable materials into tissue structures during cystoscopic procedures. It is provided sterile for single use.	To deliver a variety of legally marketed drugs into tissue structures during cystoscopic procedures. It is provided sterile for single use.
Route of Advancement:	Advanced to the lower urinary tract in tandem with a cystoscope.	Advanced to the lower urinary tract in tandem with a cystoscope
Target Populations:	Female	Female
Location of Injection:	Lower urinary tract tissue (Urethral tissues)	Lower urinary tract tissue (Bladder Wall)
Site of Use:	Hospitals, clinics, and physician offices	Hospitals, clinics, and physician offices
Device Features		
Components:	Introducer Injection Needle Fluid Ports	Introducer Injection Needle Fluid Ports Syringe
Size of Needle:	20 Ga.	23 ga.
Size of Introducer Cannula:	> 0.036 inch	0.064 inch (1.6 mm)
Connection Type(s)	Luer connector	Luer connector
Length of Needle Assembly:	12.7 cm	32.4 cm
Introducer working length	11.0 – 13.0 cm	8.06 inch (20 cm)
Introducer size (Outer Diameter)	< 8.4 mm (6.1 - 8.4 mm)	7 mm
Introducer Compatibility	Various currently marketed cystoscopes	Various currently marketed cystoscopes
Performance		
Duration of Use	≤ 24 hours	≤ 24 hours
Sterilization	Provided sterile. Sterilized by EtO	Provided sterile. Sterilized by gamma radiation (gamma).
Shelf-Life	60 Months	Not Publicly Available

Characteristic	Subject Device	Predicate Device
Device Name	**InjecSURE Injection System**	**Repris Bladder Injection System**
Frequency of Use	Single patient use.	Single patient use.
Patient Contact Materials	Evaluated in accordance with ISO 10993 for the nature and duration of contact.	Evaluated in accordance with ISO 10993 for the nature and duration of contact.

The InjecSURE Injection System is designed for use with currently marketed cystoscopes and has the same intended use and fundamental principles of operation as the predicate device. Differences in needle gauge, introducer dimensions, working length, sterilization modality, and specific anatomical site within the lower urinary tract do not constitute a new intended use and do not introduce new mechanisms of action. Performance testing demonstrates that these technological differences do not raise new questions of safety or effectiveness.

The reference devices were used solely to support certain performance test methodologies and acceptance criteria. They are not relied upon as predicate devices and are therefore not included in the substantial equivalence comparison table.

8. Performance Data

Non-clinical performance data:

The following testing has been performed to demonstrate substantial equivalence to the predicate device. The InjecSURE Injection System met all the requirements for non-clinical performance testing, confirming that the design output meets the design inputs and specifications for the device.

- Sterility Testing
  - ISO 11135:2014, ISO 11737-1:2018, ISO 11737-2:2019
- Packaging Testing
  - ISO 11607-1:2019, ISO 11607-2:2019, ASTM D4169-22 and D4332-22
- Shelf-life Testing
  - ASTM F1980-21, ASTM F88/F88M-15, ASTM F1929-23
- Dimensional Inspection and Testing
  - ISO 8600-4:2023
- Simulated Use Testing
  - ISO 62366-1:2015
- Functional Performance Testing, including:
  - Fragmentation testing (ISO 7864:2016, ISO 8871-5:2016)
  - Needle penetration force

- Needle/Hub separation (pull) force
- Cystoscope compatibility
- Irrigation flow rate
- Leakage integrity
- Visual field clearance
- Urethral insertion force

The InjecSURE Injection System met all pre-determined acceptance criteria for non-clinical performance testing and demonstrated that the device performs as intended. The results support determination that the technological differences do not raise new questions of safety or effectiveness.

Biocompatibility:

Biocompatibility studies were performed on relevant patient contacting materials in accordance with ISO 10993-1 and 2023 FDA guidance document "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process".

Clinical performance data:

No clinical study is deemed necessary since the substantial equivalence has been sufficiently demonstrated by non-clinical studies.

9. Conclusion

The InjecSURE Injection System [subject device] is substantially equivalent (SE) to the URO-1 Repris Bladder Injection System [predicate device] as they share the same intended use and fundamental principles of operation. Based on technical comparison and non-clinical performance testing described above, the technological differences do not raise new questions of safety and effectiveness.

Therefore, the InjecSURE Injection System is substantially equivalent to the referenced predicate device.