March 8, 2024

STERIS
Carroll Martin
Director, Regulatory Affairs
5976 Heisley Rd
Mentor, Ohio 44060

Re: K2328
Trade/Device Name: Articulator Injection Needle (00711807), Articulator Injection Needle (00711810), Articulator Injection Needle - enteroscope (00711808), Carr-Locke Injection Needle (00711811), Carr-Locke Injection Needle (00711812), Carr-Locke Injection Needle (00711813), Carr-Locke Injection Needle (00711814), Carr-Locke Injection Needle (00711822), Carr-Locke Injection Needle (00711823), Carr-Locke Injection Needle (00711824)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FBK
Dated: February 5, 2024
Received: February 6, 2024

Dear Carroll Martin:

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)*

K232826

Device Name

Articulator Injection Needle (00711807);
Articulator Injection Needle (00711810);
Articulator Injection Needle - enteroscope (00711808);
Carr-Locke Injection Needle (00711811);
Carr-Locke Injection Needle (00711812);
Carr-Locke Injection Needle (00711813);
Carr-Locke Injection Needle (00711814);
Carr-Locke Injection Needle (00711822);
Carr-Locke Injection Needle (00711823);
Carr-Locke Injection Needle (00711824)

Indications for Use *(Describe)*

These single use, disposable, flexible sheath injection needles are intended to be used for the injection of various types of media through flexible endoscopes.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
For the
Carr-Locke and Articulator Injection Needles
K232826

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 357-9198

Contact: Carroll Martin
Director, Regulatory Affairs

Telephone: (440) 392-7437
Fax No: (440) 358-6259
e-mail: Carroll_Martin@steris.com

Summary Date: September 13, 2023

1. Device Name

Trade Name: Articulator Injection Needle (00711807), Articulator Injection Needle (00711810), Articulator Injection Needle - enteroscope (00711808), Carr-Locke Injection Needle (00711811), Carr-Locke Injection Needle (00711812), Carr-Locke Injection Needle (00711813), Carr-Locke Injection Needle (00711814), Carr-Locke Injection Needle (00711822), Carr-Locke Injection Needle (00711823), Carr-Locke Injection Needle (00711824)

Device Class: Class II

Common/usual Name: Endoscopic Injection Needles

Regulation Name: Endoscope and accessories

Regulation Number: 21 CFR 876.1500

Product Code: FBK

2. Predicate Device

K212668 Sclerotherapy Needle

Table 1. Device Comparison Table for Carr-Locke and Articulator Needles and Predicate

Feature	Sclerotherapy Needle (Predicate Device/K212688)	Carr-Locke and Articulator Needles (Proposed Device)	Comparison
Intended Use	The device is used for endoscopic injection into gastrointestinal mucosa or to endoscopically introduce a sclerosing agent into selected sites to control actual or potential bleeding lesions in the digestive system	These single use, disposable, flexible sheath injection needles are intended to be used for the injection of various types of media through flexible endoscopes.	Similar. The predicate device mentions a sclerosing agent, but this is a type of media that is injected into the gastrointestinal tract, which both devices are intended to do.
Construction	Luer connector Handle Infusion tube Sheath Fixed button Connection tube Needle	Handle luer Handle Handle hypo tube Compression spring (all needles except P/N 00711808) PEEK tube Spring sheath Distal hub Injection needle	Similar. Although the proposed devices have a slightly different design in particular, the general design of the devices, a luer connection, a handle, a sheath, a tube through which the media flows and a needle are the same. The slight differences do not impact safety, effectiveness or how the device is used.
Sheath Diameter	1.8mm and 2.4mm	1.8mm and 2.5mm	Similar. The differences in sheath diameter between the predicate and proposed are minor. This minor difference does not impact

Feature	Sclerotherapy Needle (Predicate Device/K212688)	Carr-Locke and Articulator Needles (Proposed Device)	Comparison
			safety, effectiveness or how the device is used.
Needle Size	19 gauge 21 gauge 23 gauge 25 gauge	23 gauge 25 gauge	Same
Working Length	1200mm 1800mm 2000mm 2300mm	2300mm 3500mm	Similar. The 3500mm length of the proposed device is to allow the device to be used in an enteroscopy endoscope. Testing has shown that this difference has not impact on safety, effectiveness or how the device is used.
Packaging	Single-use EO sterilized paper-plastic pouch with one device per pouch	Single-use EO sterilized Tyvek-polyester/polyethylene film pouch. All devices are packaged 5 devices to a pouch except for P/Ns 00711810, 00711823 and 00711824 which are packaged 10 to a pouch.	Similar. The predicate and the proposed devices are packaged in sterilized pouches. The larger number of devices packaged for the proposed device does not impact safety, effectiveness or how the devices are used.
Materials	Luer connector: ABS Handle: ABS Infusion tube: PP Sheath: PTFE Fixed button: Y12Cr18Ni9Cu3 Connection tube: SUS304(06Cr19Ni10） Needle:X5CrNi18-9	Luer: polycarbonate Male handle: ABS plastic with either silver or white colorant Female handle: ABS plastic with either silver or white colorant PEEK: 381G PEEK Spring Sheath: 303 stainless steel Spring Sheath coating (PNs 00711811, 00711812, 00711813, 00711814 and 00711822): PTFE with green colorant Handle hypo tube: 304 stainless steel Distal hub: 303 stainless steel Ferrule: 304 stainless steel Compression spring: steel music wire	Similar. Both the predicate and proposed devices contain stainless steel, ABS plastic, and PTFE. The main difference is the colorant present in some of the proposed devices, but testing provided in this submission show that the colorant does not impact safety, effectiveness or how the device is used.
Sterilization Method	Ethylene Oxide	Ethylene Oxide (SAL: 10^{-6})	Same
Principle of Operation	The catheter sheath of the product is inserted into the endoscope channel. When the front part of the catheter sheath is placed	The user threads the catheter of the device through the working channel of the endoscope. Once the needle has been threaded through the	Same

Feature	Sclerotherapy Needle (Predicate Device/K212688)	Carr-Locke and Articulator Needles (Proposed Device)	Comparison
	on the lesion site, push the Luer connector for injection, the needle is exposed to the catheter sheath, and the needle is inserted into the lesion site, then drug injection.	endoscope and the injection site has been reached, the user can lock the needle into the deployed position by pressing the proximal luer against the distal luer and then turning the proximal luer until it stops. The needle can then be inserted into the mucosa of the gastrointestinal tract. Once the needle has been inserted, the desired injection media can be administered to the patient via the distal luer connection. Once injection is completed, the user can retract the needle and remove the device from the endoscope.	

The proposed devices have the same intended use as the predicate with the same technological characteristics. Based on the testing in this submission, the minor physical differences do not impact safety, effectiveness or how the devices are used.

3. Description of Device

The Carr-Locke and Articulator Injection Needles are single use, disposable, flexible sheath injection needles that are intended to be used for the injection of various types of media through flexible endoscopes. All the needles have the same general design and consist of a handle luer, a handle hypo tube, a compression spring (except for PN 00711808), a PEEK tube, a spring sheath, a distal hub and an injection needle.

The Carr-Locke and Articulator needles are sterile, disposable devices that are used through the working channel of flexible endoscopes for the purpose of injecting media into the gastrointestinal tract. Once the device is unpackaged from the sterile packaging, the user can purge the needle assembly of air by attaching the injection container (i.e. a syringe) to the proximal luer and dispensing 0.5 – 0.75 ccs of media. After purging the device, the user ensures the needle is fully retracted into the catheter of the device by slowly twisting the proximal luer until it disengages from the distal luer. Once verified that the needle has been fully retracted into the catheter, the user threads the catheter through the working channel of the endoscope. Once the needle has been threaded through the endoscope and the injection site has been reached, the user can lock the needle into the deployed position by pressing the proximal luer against the distal luer and then turning the proximal luer until it stops. The needle can then be inserted into the mucosa of the gastrointestinal tract. Once the needle has been inserted, the desired injection media can be administered to the patient via the distal luer connection. Once injection is completed, the user can retract the needle by disengaging the proximal and distal luers and allowing the compression spring to pull the needle into the sheath or by

physically grasping the proximal luer and pulling in the proximal direction until the needle enters the sheath (PN 00711808). Once the needle is retracted, the user can then remove the device from the endoscope.

4. Intended Use/Indications for Use

These single use, disposable, flexible sheath injection needles are intended to be used for the injection of various types of media through flexible endoscopes.

5. Summary of Nonclinical Tests

The Carr-Locke and Articulator Injection needles have a similar intended use and the same technological characteristics. The minor design differences and minor differences in intended use do not raise different questions of safety and effectiveness as compared to the predicate device. Testing to assess and demonstrate substantial equivalence to the predicate is summarized below:

Functional Testing		
Testing	**Acceptance Criteria**	**Results**
Working Length	Meet design requirements	Pass
Needle Deployment Length	Meet design requirements	Pass
Needle Handle Luer Compatibility	Meet design requirements	Pass
Luer Compatibility	Meet design requirements	Pass
Needle Deployment Length After Cycles	Meet design requirements	Pass
Device Insertion Force	Meet design requirements	Pass
Device Extraction Force	Meet design requirements	Pass
Pentax Needle Scope Compatibility	Meet design requirements	Pass
Device Catheter Kink Criteria	Meet design requirements	Pass
Ferrule to Needle Tensile Force	Meet design requirements	Pass
PEEK to Needle Tensile Force	Meet design requirements	Pass
Handle Hypo Tube to PEEK Tensile Force	Meet design requirements	Pass
Handle Hypo Tube to Luer Tensile Force	Meet design requirements	Pass
Distal Hub to Spring Sheath Tensile Force	Meet design requirements	Pass
Spring Sheath to Handle	Meet design requirements	Pass
Handle Hypo Tube to Washer Tensile Force	Meet design requirements	Pass
Male Handle to Female Handle Tensile Force	Meet design requirements	Pass
Injection Force Gauge Comparison	Meet design requirements	Pass
Needle Deployment Force & Retraction	Meet design requirements	Pass
Needle Leakage Test	Meet design requirements	Pass

Simulated Use Testing		
Testing	**Acceptance Criteria**	**Result**
Endoscope Channel Compatibility	Meet design requirements	Pass
Pentax Endoscope Compatibility	Meet design requirements	Pass
Duodenoscope Compatibility	Meet design requirements	Pass
Needle Deployment and Retraction	Meet design requirements	Pass
Needle Deployment Lock	Meet design requirements	Pass
Device Functions in a Straight and Articulated Position	Meet design requirements	Pass
Needle Patency	Meet design requirements	Pass
Duodenoscope Injection Compatibility	Meet design requirements	Pass
Needle Penetration	Meet design requirements	Pass
Leakage Requirement	Meet design requirements	Pass
Device Maintains Structural Integrity	Meet design requirements	Pass

6. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs at least as well as the legally marketed predicate device K212668, Class II (21 CFR 876.1500), product code FBK.