Dear Gregory Land:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

Device Name
Acu-sInQ Complete Endoscope Cleaning Aid System

Indications for Use (Describe)
The Acu-sInQ Complete Endoscope Cleaning Aid System is intended to assist manual flexible endoscope cleaning according to the instructions provided by the endoscope manufacturer, by facilitating performance of a leak test, accurate detergent dosing with water temperature monitoring, channel flushing, rinsing, and process documentation.

Type of Use (Select one or both, as applicable)
- [ ] Prescription Use (Part 21 CFR 801 Subpart D)
- [x] Over-The-Counter Use (21 CFR 801 Subpart C)

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

"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
Aqu-sInQ Complete Endoscope Cleaning Aid System

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060

Contact: Gregory Land
Senior Regulatory Affairs Specialist
Tel: 440-392-7424
Fax: 440-357-9198

Summary Date: November 9, 2018

Premarket Notification Number: K181865
1. **Device Name**

   Trade Name: Acu-sInQ Complete Endoscope Cleaning Aid System

   Device Class: II

   Common/usual Name: Circulating pump

   Classification Name: Accessories, Cleaning, For Endoscope

   Classification Number: 21 CFR 876.1500

   Product Code: FEB

2. **Predicate Device**

   US Endoscopy Fluid Pump CP-3, cleared under K914524.

3. **Description of Device**

   The Acu-sInQ Complete Endoscope Cleaning Aid System is used in the reprocessing room of a hospital or endoscopy center, and aids technicians by providing a step-by-step cleaning sequence of flexible endoscopes for process management and reports.

   The Acu-sInQ Complete Endoscope Cleaning Aid System is a 4-in-1 system with automated scope inflation for performance of a leak test, precision chemical dosing, and automated channel flushing with pulsating fluid technology for main and auxiliary flush ports. The System also provides:

   - Data management via printout with every cycle
   - USB drive and port output for capture and recording of process data and chemical usage
   - Software to enable transfer of data between system and Customer’s PC
   - Barcode scanner to input endoscope serial number and technician ID which aids in documentation process
   - Pre-loading with Customer’s endoscope inventory

4. **Indications for Use**

   The Acu-sInQ Complete Endoscope Cleaning Aid System is intended to assist manual flexible endoscope cleaning according to the instructions provided by the endoscope manufacturer, by facilitating performance of a leak test, accurate
detergent dosing with water temperature monitoring, channel flushing, rinsing, and process documentation.

5. **Technical Characteristics Comparison Table**

A comparison of technical characteristics versus the predicate is summarized in Table 5-1

**Table 5-1.** Physical Description and Technological Properties vs the Predicate Device.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Acu-sInQ Complete Endoscope Cleaning Aid (proposed)</th>
<th>Fluid Pump CP-3 Predicate (K914524)</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for Use</td>
<td>The Acu-sInQ Complete Endoscope Cleaning Aid System is intended to assist manual flexible endoscope cleaning according to the instructions provided by the endoscope manufacturer, by facilitating performance of a leak test, accurate detergent dosing with water temperature monitoring, channel flushing, rinsing, and process documentation.</td>
<td>The Fluid pump CP #3 is intended to pump fluid media thru the channels of endoscope and accessories with lumens. The various fluid media that are compatible are soapy water, enzyme/water solution, water, 70% alcohol, and liquid disinfectants. The pump will also pump minimal amounts of air to help purge the channels or lumens of droplets of fluid media. Consult with instrument manufacturer for fluid media compatibility.</td>
<td>Both devices are intended to flush fluid through the channel of an endoscope to aid in the manual cleaning process. The subject device has the added functionality to assist the user with additional steps of the endoscope cleaning process, leak test, detergent dosing and temperature monitoring.</td>
</tr>
<tr>
<td>Feature</td>
<td>Acu-sInQ Complete Endoscope Cleaning Aid (proposed)</td>
<td>Fluid Pump CP-3 Predicate (K914524)</td>
<td>Comparison</td>
</tr>
<tr>
<td>---------</td>
<td>--------------------------------------------------</td>
<td>-------------------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Operating Principles/Technology</td>
<td>A microprocessor controlled unit operates internal pumps to aid in the cleaning of endoscopes. An internal air pump pressurizes an endoscope through a dedicated leak test tubing to perform a leak test. A detergent tube is placed in a container of detergent and a peristaltic pump pulls the detergent through the tubing, the detergent is then expelled through a discharge tube into the cleaning solution. A tubing set pulls fluid from the cleaning solution through a peristaltic pump and discharge tubing set where it is expelled through the endoscope channels.</td>
<td>Flushing fluids are placed into a container, pre-cleaning basin or sink. A tubing set pulls fluid from the container, basin, or sink into and through an internal fluid pump. The fluid is then expelled from the pumps through discharge tubing sets which are connected to the endoscope channels. The fluid is then pumped through the endoscope channels.</td>
<td>Both devices utilize electronically controlled flush pumps to flush fluid through the channels of an endoscope. The predicate device is controlled through analog circuits while the subject device uses software.</td>
</tr>
<tr>
<td>Software Controlled User Interface</td>
<td>Yes</td>
<td>No</td>
<td>The subject device uses software to control the unit whereas the predicate device uses analog circuits to control to device.</td>
</tr>
<tr>
<td>Fluid Delivery Flow Rate</td>
<td>Meet or exceed the endoscope manufacturer’s requirements for fluid delivery through endoscope channels</td>
<td>Meet or exceed the endoscope manufacturer’s requirements for fluid delivery through endoscope channels</td>
<td>Same</td>
</tr>
<tr>
<td>Mechanism of Action</td>
<td>Software controlled air pump, peristaltic pump and flush pump</td>
<td>Internal flush pumps with built-in timer</td>
<td>Like the predicate device the subject device has a flush pump. Additionally the subject device uses an air pump and peristaltic pump for leak testing and detergent dosing.</td>
</tr>
<tr>
<td>Feature</td>
<td>Acu-sInQ Complete Endoscope Cleaning Aid (proposed)</td>
<td>Fluid Pump CP-3 Predicate (K914524)</td>
<td>Comparison</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>Amount of Cleaning Liquid</td>
<td>Amount sufficient to meet or exceed the endoscope manufacturer’s requirements for volume of fluid delivery through endoscope channels.</td>
<td>Amount sufficient to meet or exceed the endoscope manufacturer’s requirements for volume of fluid delivery through endoscope channels.</td>
<td>Same</td>
</tr>
<tr>
<td>Time for Cleaning Liquid</td>
<td>Variable, the length of the cleaning liquid circulation time is determined by setting a timer.</td>
<td>Variable, the length of the cleaning liquid circulation time is determined by setting a timer.</td>
<td>Same</td>
</tr>
</tbody>
</table>

6. **Summary of Nonclinical Tests**

The non-clinical performance testing demonstrated that the subject device met the acceptance criteria for each test that is identified and summarized in Table 5-2 below.

**Table 5-2. Summary of Non-clinical Testing**

<table>
<thead>
<tr>
<th>Test</th>
<th>Acceptance Criteria</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluid Flushing (open)</td>
<td>Device provides consistent fluid flushing volume when not connected to an endoscope.</td>
<td>PASS</td>
</tr>
<tr>
<td>Fluid Flushing (Endoscope)</td>
<td>Device provides consistent fluid flushing volume when connected to an endoscope.</td>
<td>PASS</td>
</tr>
<tr>
<td>Dosing</td>
<td>Accuracy of dose of ± 5%</td>
<td>PASS</td>
</tr>
<tr>
<td>Temperature Accuracy</td>
<td>Accuracy of temperature of ± 5%</td>
<td>PASS</td>
</tr>
<tr>
<td>Electrical Safety</td>
<td>Compliant with IEC 61010-1</td>
<td>PASS</td>
</tr>
<tr>
<td>Electromagnetic Compatibility</td>
<td>Compliant with IEC 61326-1</td>
<td>PASS</td>
</tr>
</tbody>
</table>

7. **Conclusion**

Based on the conclusions from the non-clinical performance data, the subject device is as safe, as effective and performs as well as or better than the legally marketed predicate device (K914524), Class II (21 CFR 876.1500), product code FEB.