October 17, 2019

Reach Surgical, Inc.
℅ Rich Grant
Official Correspondent
SeCQure Surgical
4480 Lake Forest Dr.
Cincinnati, Ohio 45242

Re: K192566
Trade/Device Name: Reach and CQ'ENCE Circular Staplers
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: September 6, 2019
Received: September 18, 2019

Dear Rich Grant:

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.


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,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K192566

Device Name
CQ'ENCE™ Circular Staplers

Indications for Use (Describe)
The CQ'ENCE Circular Staplers have application throughout the alimentary tract for the creation of end-to-end, side-to-side and end-to-side anastomoses in both open and laparoscopic surgeries.

Type of Use (Select one or both, as applicable)

- [X] 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.*

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I. SUBMITTER

Rach Surgical Inc.
120 XinXing Road
West Zone, TEDA
Tianjin, Tianjin CHINA 300462

Contact Person:
Richard Grant
Phone: 513-608-4017
Email: rgrant@secquresurgical.com

Date Prepared: September 6, 2019

II. DEVICE

Name of Device: Reach™ and CQ'ENCE™ Circular Stapler
Common or Usual Name: Circular Stapler
Classification Name: Staple, implantable (21 CFR 878.4750)
Regulatory Class: II
Product Code: GDW

III. PREDICATE DEVICE

REACH™ Circular Staplers, (K120179)

IV. DEVICE DESCRIPTION

The REACH™ and SeCQure CQ’ENCE™ Circular Staplers (CQ’ENCE™ Circular Staplers) are sterile, single-use, hand-held, non-powered stapling devices used during general surgical procedures for the creation of end-to-end, side-to-side and end-to-side anastomoses in both open and laparoscopic surgeries.

The Circular Staplers place a double-staggered, circular row of titanium staples while simultaneously resecting tissue when the device is manually activated. The device is provided in five head diameter sizes: 34mm, 31mm, 28mm, 25mm, and 21mm (product codes CS34, CS31, CS28, CS25, and CS21 respectively). Each size device can be purchased with a standard 27cm length shaft. The CS21 and SC25 can also be purchased with a longer, 35cm shaft (product codes CS21L, CS25L) to facilitate surgeon access to desired tissues.

The CQ’ENCE™ Circular Stapler allows the surgeon to control tissue compression by varying the closed staple height. The CQ’ENCE Circular Stapler forms traditional B-shaped staples that are comprised of titanium. Safe removal of the device is facilitated by opening the instrument one full turn or until the Audible Indicator makes a clicking sound.

V. INDICATIONS FOR USE
The CQ’ENCE Circular Staplers have application throughout the alimentary tract for the creation of end-to-end, side-to-side and end-to-side anastomoses in both open and laparoscopic surgeries.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Reach™ and CQ’ENCE™ Circular Stapler has the same technological characteristics as the predicate device with the exception of an additional device size and minor technological characteristics as described below

*Table 1: Technological Characteristics*

<table>
<thead>
<tr>
<th>Product</th>
<th>Reach™ and SeCQure CQ’ENCE™ Circular Stapler (Subject)</th>
<th>Predicate Reach™ Circular Stapler (K120179)</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anatomical Site Used</td>
<td>Various soft tissues accessible during laparoscopic procedures</td>
<td>Various soft tissues accessible during laparoscopic procedures</td>
<td>Same</td>
</tr>
<tr>
<td>Product Models Provided</td>
<td>SeCQure CQ’ENCE™ ¹ CS34, CS31, CS28, CS25, CS25L, CS21, CS21L</td>
<td>RCS34D, RCS31G, RCS28G, RCS25G, RCS25G, RCS23G, RCS17G</td>
<td>Equivalent. The subject device is provided in a 21mm size which is within the previously cleared range and was cleared in K071023. The 17 mm size is discontinued. The models are available in two brand types, Reach™ or SeCQure CQ’ENCE™, which are the same with the exception of branding.</td>
</tr>
<tr>
<td>Cutting Mechanism</td>
<td>Circular Knife</td>
<td>Circular Knife</td>
<td>Same</td>
</tr>
<tr>
<td>Method of Activation</td>
<td>Single Trigger manually activated</td>
<td>Single Trigger manually activated</td>
<td>Same</td>
</tr>
<tr>
<td>Disposable/Reusable</td>
<td>Disposable</td>
<td>Disposable</td>
<td>Same</td>
</tr>
<tr>
<td>Safety Mechanism</td>
<td>Firing Safety with Out-of-Range Lockout</td>
<td>Firing Safety with Out-of-Range Lockout</td>
<td>Same</td>
</tr>
<tr>
<td>Main Device Features/Components</td>
<td>Anvil Cartridge</td>
<td>Anvil Cartridge</td>
<td>Same</td>
</tr>
</tbody>
</table>

¹ Note: The Reach and SeCQure CQ’ENCE™ products are the same products with different branding i.e. the CS34 is the 34mm size SeCQure branded CQ’ENCE™ Stapler and the ACS34D is the 34mm size Reach™ branded CQ’ENCE™ Stapler. The devices are the same other than the branding on the labels and pad printed branding on the handles.
<table>
<thead>
<tr>
<th>Feature</th>
<th>Instrument Shaft</th>
<th>Instrument Shaft</th>
<th>Equivalent. A biocompatible lubricant was added to the manufacturing process in the current configuration.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Materials</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staples</td>
<td>ASTM F 67 Unalloyed Titanium</td>
<td>Staples: ASTM F 67 Unalloyed Titanium</td>
<td></td>
</tr>
<tr>
<td>End Effector</td>
<td>polycarbonate and stainless steel</td>
<td>End Effector: polycarbonate and stainless steel</td>
<td></td>
</tr>
<tr>
<td>Shaft</td>
<td>stainless steel</td>
<td>stainless steel</td>
<td></td>
</tr>
<tr>
<td>Handle</td>
<td>polycarbonate</td>
<td>polycarbonate</td>
<td></td>
</tr>
<tr>
<td>Lubricant</td>
<td>PTFE &amp; Silicone Grease</td>
<td>Silicone Grease</td>
<td></td>
</tr>
<tr>
<td><strong>Staple Shape</strong></td>
<td>Standard “B” shaped staple</td>
<td>Standard “B” shaped staple</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Staple Height (open)</strong></td>
<td>3.5 and 4.8 mm</td>
<td>3.5 and 4.8 mm</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Staple Height (closed)</strong></td>
<td>1.0 to 1.8 for 3.5 mm Staples</td>
<td>1.5 and 2.2 mm</td>
<td>Same staple height. The Staple Height labeling has been amended to align with industry standard to describe the range of staple heights to be selected by the user. The staple height remains adjustable in the control of the user.</td>
</tr>
<tr>
<td><strong>End Effector Diameters</strong></td>
<td>34mm, 31mm, 28mm, 25mm, and 21mm</td>
<td>34mm, 31mm, 28mm, 25mm, 23mm and 17 mm</td>
<td>Equivalent. The subject device is provided in a 21mm size which is within the previously cleared range. The 17 mm size is being discontinued.</td>
</tr>
<tr>
<td><strong>Shaft Length</strong></td>
<td>Standard (27cm), Long (35 cm)</td>
<td>Standard (27cm), Long (35 cm)</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Markings on Shaft</strong></td>
<td>5, 10, 15, 20, and 25mm marks</td>
<td>5, 10, 15, 20, and 25mm marks</td>
<td>Same</td>
</tr>
</tbody>
</table>
VII. PERFORMANCE DATA

Reach™ Circular Stapler performance bench testing was provided in K120179. Testing for the Reach™ and CQ’ENCE™ Circular Stapler is provided in Section 018 – Performance Testing - Bench of this submission to the same specifications as the Reach™ Circular Stapler previously provided in K120179. The data demonstrates that the Reach™ and CQ’ENCE™ Circular Stapler meets the same specifications for visual inspection, dimensional analysis, staple form and safety mechanism performance. The materials used in the device, packaging, and sterilization method remain unchanged.

VIII. CONCLUSIONS

The CQ’ENCE™ Circular Stapler has the same intended use and principles of operation as its predicate device. The minor differences in technological characteristics do not change the device use or application and have been tested to the same standards as the currently marketed devices. There are no new issues of safety or effectiveness. The CQ’ENCE™ Circular Stapler is substantially equivalent to the predicate device.

<table>
<thead>
<tr>
<th>Markings on Handle</th>
<th>Printed instructions for opening</th>
<th>None</th>
<th>Equivalent. Printed instructions were added for ease of use.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anvil Tilt</td>
<td>Anvil Tilt Feature not offered</td>
<td>Anvil Tilt Feature offered</td>
<td>Equivalent. The Anvil Tilt feature is no longer offered as non-tilting is a standard for circular staplers.</td>
</tr>
<tr>
<td>Opening Method</td>
<td>Turn the Wing Nut counterclockwise one half to a full turn until the Audible Indicator clicks</td>
<td>Turn the Wing Nut counterclockwise one half to a full turn</td>
<td>Equivalent. Opening is the same. An audible click has been added to indicate to the user when the device is fully open.</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Stapler is biocompatible for blood/bone/tissue contact for limited duration Staples are biocompatible for permanent implantation</td>
<td>Stapler is biocompatible for blood/bone/tissue contact for limited duration Staples are biocompatible for permanent implantation</td>
<td>Same</td>
</tr>
<tr>
<td>Endotoxin Limit</td>
<td>0.5 EU/mL (20 EU/Device)</td>
<td>0.5 EU/mL (20 EU/Device)</td>
<td>Same</td>
</tr>
<tr>
<td>Sterilization Method</td>
<td>EtO, SAL 10⁻⁶</td>
<td>EtO. SAL 10⁻⁶</td>
<td>Same</td>
</tr>
<tr>
<td>Packaging</td>
<td>Tyvek covered tray in cardboard box</td>
<td>Tyvek covered tray in cardboard box</td>
<td>Same</td>
</tr>
<tr>
<td>Shelf Life</td>
<td>5 years</td>
<td>5 years</td>
<td>Same</td>
</tr>
</tbody>
</table>