September 29, 2017

CPT Sutures Co., Ltd.
% Ms. Natalya Valerio
Official Correspondent for CPT Sutures Co., Ltd.
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K170166
Trade/Device Name: CARESORB® - Polylactin 910 Surgical Suture, CARESORB RAPID® - Polylactin 910 (fast Absorbing) Surgical Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: August 31, 2017
Received: September 1, 2017

Dear Ms. Valerio:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbrading 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Device Name
CARESORB® - Polyglactin 910 Surgical Suture

Indications for Use (Describe)

CARESORB® - Polyglactin 910 Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures; but not for use in cardiovascular or neurological tissues.
Indications for Use

510(k) Number (if known)
K170166

Device Name
CARESORB® RAPID - Polylactin 910 (fast absorbing) Surgical Suture

Indications for Use (Describe)

CARESORB® RAPID Polylactin 910 (fast absorbing) Surgical Sutures are indicated for use in superficial soft tissue approximation of the skin and mucosa, where only short-term wound support (7-10 days) is required, but not for use in ligation, ophthalmic, cardiovascular or neurological procedures.

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."

FORM FDA 3881 (8/14)  Page 1 of 1
510(k) SUMMARY

The assigned 510(k) number is: K170166

1. **Submitter’s Identification:**

   CPT Sutures Co., Ltd.
   8 Dao Tri Street
   Phu Thuan Ward
   District 7, Ho Chi Minh, Vietnam

   Date Summary Prepared: August 31, 2017

   **Contact:** Mr. Khoa Do
   Vice Director
   CPT Sutures Co., Ltd.
   e-mail: khoa.do@cpt-medical.com
   phone: (+84) 28 38 222 228

2. **Name of the Device:**

   Trade Name: CARESORB® - Polyglactin 910 Surgical Suture and
   CARESORB® RAPID - Polyglactin 910 fast absorbing
   Surgical Suture
   Common Name: Suture, Absorbable, Synthetic, Polyglycolic Acid
   Regulation Number: 21CFR 878.4493
   Regulation Name: Absorbable Poly(glycolide/L-lactide) Surgical Suture
   Regulatory Class: Class II
   Product Code: GAM

3. **Information for the 510(k) Cleared Device (Predicate Device):**

   Ethicon’s Coated VICRYL™ (Polyglactin 910) Synthetic Absorbable Suture, 510(k) # K022269

   Ethicon’s Coated VICRYL™ Rapide (Polyglactin 910) Synthetic Absorbable Suture, 510(k) # K033746

4. **Device Description:**

   The CARESORB® - Polyglactin 910 and CARESORB® RAPID - Polyglactin 910 are multifilament, braided, sterile synthetic absorbable surgical sutures composed of a copolymer of 90% glycolide and 10% L-lactide. The CARESORB® - Polyglactin 910 and CARESORB® RAPID - Polyglactin 910 are coated with copolymer of Poly(glycolide-co-L-lactide) (30/70) and calcium stearate.

   The CARESORB® - Polyglactin 910 suture is available dyed with FDA-approved color additive D&C Violet No. 2 - CI 60725 or undyed in the natural beige color.
The CARESORB® RAPID - Polyglactin 910 suture is available undyed in the natural beige color only.

The CARESORB® sutures are available in USP sizes 6-0 through 1 and CARESORB® RAPID sutures in USP sizes 4-0 through 2-0, in different lengths, with or without a standard needle attached.

The CARESORB® and CARESORB® RAPID sutures meet USP Monograph for Synthetic Absorbable Sutures, except for diameter.

5. **Indications for Use:**

**CARESORB®** - Polyglactin 910 Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures; but not for use in cardiovascular or neurological tissues.

**CARESORB® RAPID** - Polyglactin 910 (fast absorbing) Surgical Sutures are indicated for use in superficial soft tissue approximation of the skin and mucosa, where only short-term wound support (7-10 days) is required, but not for use in ligation, ophthalmic, cardiovascular or neurological procedures.

6. **Comparison to the 510(k) Cleared Devices (Predicate Devices):**

<table>
<thead>
<tr>
<th>Comparison Criteria</th>
<th>New Device CARESORB® - Polyglactin 910 Surgical Suture</th>
<th>New Device CARESORB® RAPID - Polyglactin 910 Surgical Suture</th>
<th>Predicate Device(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Predicate Device</strong></td>
<td>Ethicon’s Coated VICRYL™ (Polyglactin 910) Synthetic Absorbable Suture, 510(k) # K022269</td>
<td>Ethicon’s Coated VICRYL™ Rapide (Polyglactin 910) Synthetic Absorbable Suture, 510(k) # K033746</td>
<td>![ ]</td>
</tr>
<tr>
<td><strong>Classification</strong></td>
<td>Synthetic Absorbable Surgical Suture</td>
<td>Synthetic Absorbable Surgical Suture</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Indications for Use</strong></td>
<td>General soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not in cardiovascular or neurological tissues</td>
<td>Superficial soft tissue approximation of the skin and mucosa, where only short-term wound support (7-10 days) is required but not for use in ligation, ophthalmic, cardiovascular or neurological procedures</td>
<td>Same for each respective predicate</td>
</tr>
<tr>
<td><strong>Suture Material</strong></td>
<td>Copolymer of 90% glycolide and 10% L-lactide</td>
<td>Copolymer of 90% glycolide and 10% L-lactide</td>
<td>Same</td>
</tr>
<tr>
<td>Material Presentation</td>
<td>Multifilament, braided</td>
<td>Multifilament, braided</td>
<td>Same for each respective predicate</td>
</tr>
<tr>
<td>-----------------------</td>
<td>------------------------</td>
<td>------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Coating</td>
<td>Coated with copolymer of Poly(glycolide-co-L-lactide) (30/70) and calcium stearate</td>
<td>Coated with copolymer of Poly(glycolide-co-L-lactide) (30/70) and calcium stearate</td>
<td>Same</td>
</tr>
<tr>
<td>Color Additive</td>
<td>Available dyed with FDA-approved color additive D&amp;C Violet No. 2 - CI 60725 as well as undyed in natural beige color</td>
<td>Available undyed only</td>
<td>Same for each respective predicate</td>
</tr>
<tr>
<td>Sterilization</td>
<td>Sterilized by Ethylene Oxide</td>
<td>Sterilized by Ethylene Oxide</td>
<td>VICRYL™ is sterilized by Ethylene Oxide VICRYL™ Rapide is sterilized by Gamma Irradiation</td>
</tr>
<tr>
<td>Single Use</td>
<td>Yes</td>
<td>Yes</td>
<td>Same</td>
</tr>
<tr>
<td>How Supplied</td>
<td>Sutures of various lengths and gauge sizes of USP 6-0 to 1, with or without the standard stainless steel needle (series 302 with silicon coating) attached. Available as one-dozen and three-dozen boxes.</td>
<td>Sutures of various lengths and gauge sizes of USP 4-0 to 2-0, with or without the standard stainless steel needle (series 302 with silicon coating) attached. Available as one-dozen and three-dozen boxes.</td>
<td>Sutures of various gauge sizes and lengths, with or without standard stainless steel needle attached. Available as one-dozen and three-dozen boxes.</td>
</tr>
<tr>
<td>Absorption Profile</td>
<td>Suture absorption begins as a loss of tensile strength followed by eventual absorption by hydrolysis. Complete absorption occurs between 56-70 days.</td>
<td>Suture absorption begins as a loss of tensile strength followed by eventual absorption by hydrolysis. Complete absorption occurs in 42 days.</td>
<td>Same for each respective predicate</td>
</tr>
<tr>
<td>Breaking Strength Retention Profile</td>
<td>Percent Breaking Strength Retention (% BSR): &gt; 65% at 14 days; &gt; 40% at 21 days.</td>
<td>Percent Breaking Strength Retention (% BSR): 50% at 5 days; 0% at 14 days.</td>
<td>Same for each respective predicate</td>
</tr>
<tr>
<td>Suture Diameter</td>
<td>Complies with USP &lt;861&gt; except for slight oversize in the suture diameter</td>
<td>Complies with USP &lt;861&gt; except for slight oversize in the suture diameter</td>
<td>Same</td>
</tr>
<tr>
<td>Suture Length</td>
<td>≥ 95% of the claimed label length as required by USP</td>
<td>≥ 95% of the claimed label length as required by USP</td>
<td>Same</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------------------------------------------</td>
<td>---------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>Needle Attachment</td>
<td>Complies with USP &lt;871&gt;</td>
<td>Complies with USP &lt;871&gt;</td>
<td>Same</td>
</tr>
<tr>
<td>Tensile Strength</td>
<td>Complies with USP &lt;881&gt;</td>
<td>Complies with USP &lt;881&gt;</td>
<td>Same</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Complies with all ISO 10993-1 required tests for absorbable surgical sutures</td>
<td>Complies with all ISO 10993-1 required tests for absorbable surgical sutures</td>
<td>Same</td>
</tr>
<tr>
<td>Packaging</td>
<td>Validated sterile barrier packaging system</td>
<td>Validated sterile barrier packaging system</td>
<td>Same</td>
</tr>
</tbody>
</table>

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence:**

The below referenced testing demonstrated substantial equivalence of the CARESORB® - Polyglactin 910 Surgical Suture and CARESORB® RAPID - Polyglactin 910 (fast absorbing) Surgical Suture to the Ethicon’s Coated VICRYL™ and Ethicon’s Coated VICRYL™ Rapide predicate devices respectively. The testing was conducted on the final sterilized devices in accordance with the FDA Class II Special Controls Guidance Document: Surgical Sutures.

**Performance Testing:**

1) ISO 10993-3 Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity, 2014

2) ISO 10993-5 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity, 2009 (R) 2014

3) ISO 10993-6 Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects after Implantation, 2007 (R) 2014

4) ISO 10993-7 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals, 2008 (R) 2012

5) ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization, 2010 (R) 2014

7) USP 39-NF33 Absorbable Surgical Suture, 2016

8) USP 39-NF33 <861> Sutures – Diameter, 2016

9) USP 39-NF33 <871> Sutures – Needle Attachment, 2016

10) USP 39-NF33 <881> Tensile Strength, 2016

11) ISO 11607-1 Section 5.2 Whole package microbial aerosol challenge test, 2014


14) ASTM F2096-11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test), 2011

15) USP39-NF 34 <71> Sterility Test, 2016

16) USP39-NF 34 <85> Bacterial Endotoxins Test, 2016

17) ISO 15223-1 Third Edition 2016-11-01, Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements. (General I (QS/RM))

The biocompatibility test results demonstrated no evidence of cytotoxicity, irritation, delayed dermal sensitization or acute systemic toxicity for CARESORB® Surgical Suture. In the short-term, mid-term and long-term Intramuscular Implantation Tests with Histopathology, the CARESORB® Surgical Suture was considered a non-irritant as compared to the predicate VICRYL™ used as a control. In the mid-term Intramuscular Implantation Test with Histopathology, the CARESORB® Rapid Surgical Suture was considered a non-irritant as compared to the predicate VICRYL™ Rapide used as a control.

The CARESORB® Suture was also found to be non-pyrogenic, non-mutagenic and non-genotoxic.
Resorption Profile:

The resorption profiles of the final sterilized sutures were demonstrated in vivo.

The CARESORB® sutures were compared to the predicate VICRYL™ sutures in the in-vivo implantation study. The study results demonstrated that CARESORB® sutures have similar tensile strength retention profile in comparison to the marketed predicate VICRYL™ sutures.

The in-vivo breaking strength retention profile of CARESORB® RAPID was based on the data provided by the suture material supplier from the in-vivo implantation study. The resorption profile of CARESORB® RAPID was determined to be similar to that of the marketed predicate VICRYL™ Rapide.

The resorption profile of the final sterilized CARESORB® RAPID suture was also demonstrated in vitro.

The CARESORB® RAPID, sterilized by EtO, were compared to the predicate VICRYL™ Rapide sutures, sterilized by gamma irradiation, and to the raw material supplier’s sutures, sterilized by gamma irradiation. All sutures were immersed in the phosphate buffer solution (pH 7.4) for 5, 14, 21 and 28 days and then tested for breaking strength retention at each time point. The study results demonstrated that all three sutures had essentially identical resorption profiles under the same study conditions and that tensile strength and tensile strength retention of CARESORB® RAPID was comparable to those of VICRYL™ Rapide and the raw material supplier’s sutures.

Additionally, the rate of absorption of CARESORB® sutures was compared to that of predicate VICRYL™ sutures in the in-vivo implantation study. The study results demonstrated that CARESORB® sutures and VICRYL™ sutures have very similar absorption in tissue.

The rate of absorption of CARESORB® RAPID was based on the data provided by the suture material supplier from the in-vivo implantation study. The CARESORB® RAPID rate of absorption in tissue was determined to be similar to that of the marketed predicate VICRYL™ Rapide.

Shelf Life:

CARESORB® and CARESORB® RAPID sutures have been tested in real time stability studies as well as in the accelerated aging studies.

The real time stability studies for both sutures were performed at 18°C to 26°C temperature and relative humidity of no more than 65%. The accelerated aging stability studies were performed at 68°C to 72°C temperature and relative humidity of no more than 65% for CARESORB® and at 53°C to 57°C temperature and relative humidity of no more than 65% for CARESORB® RAPID.

The aged sutures were tested for parameters specified in the USP Monograph for Absorbable Surgical Sutures and other applicable requirements:
- Diameter, USP 39 <861>
- Needle Attachment, USP 39 <871>
- Tensile Strength, USP 39 <881>
- In vitro Breaking Strength Retention (BSR)
- Visual Inspection
- Moisture content
- Sterility Testing, USP 39-NF34 <71>

The study results demonstrated conformance to the specified acceptance criteria and supported the 5 year expiration date assignment for CARESORB® and CARESORB® RAPID sutures.

8. **Discussion of Clinical Tests Performed:**

Not Applicable

9. **Conclusions:**

The CARESORB® - Polyglactin 910 and CARESORB® RAPID - Polyglactin 910 Surgical Sutures are composed of the same material, have the same intended use and main technological characteristics as their respective predicate devices Ethicon’s Coated VICRYL™ and Ethicon’s Coated VICRYL™ Rapide Surgical Sutures.

Based on the results of completed performance testing inclusive of physical testing, biocompatibility testing and absorption profile, it can be concluded that CARESORB® - Polyglactin 910 and CARESORB® RAPID - Polyglactin 910 are substantially equivalent in terms of safety and effectiveness to Ethicon’s Coated VICRYL™ and Ethicon’s Coated VICRYL™ Rapide respectively.