March 26, 2018

CP Medical Inc.
Mr. John Hartigan
Director QA/RA
1775 Corporate Dr.
Suite 150
Norcross, Georgia 30093

Re: K173922
Trade/Device Name: C-PTFE™ Surgical Suture
Regulation Number: 21 CFR 878.5035
Regulation Name: Nonabsorbable Expanded Polytetrafluoroethylene Surgical Suture
Regulatory Class: Class II
Product Code: NBY
Dated: December 21, 2017
Received: December 26, 2017

Dear Mr. Hartigan:

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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Jennifer R. Stevenson -S3

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173922

Device Name
C-PTFETM Surgical Suture

Indications for Use *(Describe)*
The CP Medical nonabsorbable C-PTFETM Surgical Suture is a removable, nonabsorbable surgical suture intended for use in general soft tissue approximation and/or ligation, including dental surgical procedures. CP Medical C-PTFETM sutures are contra indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissue.

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."

1. 510(k) Summary

In accordance with 21 CFR 807.87 (h) and 21 CRF 807.92, the 510(k) summary for the C-PTFE® Surgical Suture is provided below.

Date Summary Prepared	December 14, 2017
Manufacturer/Distributor/ Sponsor	CP Medical Inc. 1775 Corporate Drive, Ste. 150 Norcross, GA 30093
510(k) Contact	CP Medical John Hartigan 1775 Corporate Drive Norcross, GA 30093 470-273-6005 (phone) hartiganj@cpmedical.com (email)
Trade Name	*C-PTFE™ Surgical Suture*
Common Name	Surgical Suture, Nonabsorbable
Code –Name – Classification	**NBY** – Surgical Suture Class II: 21 CFR §878.5035
Predicate Devices	MonoTex K140415 This predicate has not been subject to a design-related recall (FDA's TPLC website,. no filings from 2000 to date 2017)
Device Description	Device Description: The CP Medical C-PTFE™ Surgical Sutures are Nonabsorbable, Polytetraflouroethylene, single use, sterile, disposable, monofilament sutures and are provided with or without needles. Individual sutures are available in a "racetrack" configuration, attached around a HDPE delivery system, and/or in a figure 8 in a Tyvek/film pouch. The CP Medical C-PTFE™ Surgical Sutures are sterilized via EO in accordance with EN ISO-11135:2014
Intended Use	CP Medical nonabsorbable C-PTFE™ Surgical Suture is a removable, nonabsorbable surgical suture intended for use in general soft tissue approximation and/or ligation, including dental surgical procedures. CP Medical C-

	PTFE™ sutures are contra indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissue.
Non-Clinical Performance Testing	The CP Medical nonabsorbable C-PTFE™ Surgical Suture was tested recognized standard *6-393: USP-40-NF35:2017, Nonabsorbable Surgical Suture, 6-394: USP-40-NF35:2017, <881>, Tensile Strength, 6-395: USP-40-NF35:2017 <861>, Diameter, 6-396 USP-40-NF35:2017 <871>, Sutures – Needle Attachment.*
Substantial Equivalence Summary (Conclusion)	Based on the technological; characteristics and non-clinical performance testing the CP Medical C-PTFE™ Surgical Suture was shown to be substantially equivalent to the predicate device, the MonoTex K140415.

Additionally, a comparison between the CP Medical C-PTFETM Surgical Suture and the predicate device is summarized below:

Feature	CP Medical C-PTFE™ Surgical Suture	MonoTex K140415	Substantially Equivalent
Device Classification	Class II: 21 CFR §878.5035	Class II: 21 CFR §878.5035	Yes
Product Code	NBY – Suture Surgical	NBY – Suture Surgical	Yes
Device Common Name as Cleared by FDA	Suture, Surgical Nonabsorbable, Polytetraflouroethylene	Suture, Surgical Nonabsorbable, Polytetraflouroethylene	Yes
Indications for use	CP Medical nonabsorbable C-PTFE™ Surgical Suture is a removable, nonabsorbable surgical suture intended for use in general soft tissue approximation and/or ligation, including dental surgical procedures. CP Medical C-PTFE™ sutures are contra indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissue.	Riverpoint MonoTex surgical suture is indicated for use in general soft tissue approximation and/or ligation, including cardiovascular, dental, general surgical procedures and repair of dura matter. Riverpoint MonoTex sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissue	Yes
Patient Population	Single use only	Single use only	Yes
Environment of Use	Point of procedure – clinical settings.	Point of procedure – clinical settings.	Yes

Feature	CP Medical C-PTFE™ Surgical Suture	MonoTex K140415	Substantially Equivalent
Device Description	CP Medical C-PTFE™ Surgical Suture are sterile, nonabsorbable, monofilament sutures available with or without needles, The sutures are delivered in a figure 8 or racetrack configuration, which is contained within a Tyvek/film package. The sutures are sterilized by EO.	Riverpoint PTFE MonoTex Surgical Suture are sterile, nonabsorbable, monofilament sutures available with or without needles, The sutures are delivered in a figure 8 or racetrack configuration, which is contained within a Tyvek/film package. The sutures are sterilized by EO.	Yes
Principles of Operation	CP Medical C-PTFE™ Surgical Suture are for use in clinical settings and carry a prescription. The sutures are removed for device packing following aseptic protocols.	Riverpoint PTFE MonoTex Surgical Suture are for use in clinical settings and carry a prescription. The sutures are removed for device packing following aseptic protocols.	Yes
Sizes	Various diameters based on USP (unless stated on labeling), various lengths.	Various diameters based on USP (unless stated on labeling), various lengths.	Yes
Needles	Available with or without standard needles attached.	Available with or without standard needles attached.	Yes
Colors available	White/Undyed	White/Undyed	Yes

Feature	CP Medical C-PTFE™ Surgical Suture	MonoTex K140415	Substantially Equivalent
Non-Clinical Testing Summary	The CP Medical nonabsorbable C-PTFE™ Surgical Suture was tested per recognized standard: • 6-393: USP-40-NF35:2017, Nonabsorbable Surgical Suture, • 6-394: USP-40-NF35:2017, <881>, Tensile Strength. • 6-395: USP-40-NF35:2017 <861>, Diameter • 6-396 USP-40-NF35:2017 <871>, Sutures – Needle Attachment.	Riverpoint PTFE MonoTex are tested per USP <861>, <871> and <881>.	Yes – Test report 17-033 confirmed equivalency.
Sterile	Yes	Yes	Yes
Sterilization method	EO	EO	Yes
Biocompatible materials	Per ISO 10993	Per ISO 10993	Yes
Instructions for Use	Yes	Yes	Yes
Materials	Monofilament Polytetraflouroethylene	Monofilament Polytetraflouroethylene	Yes
RX	Yes	Yes	Yes

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for CP Medical C-PTFE™ was conducted in accordance with FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk management Process," as recognized by FDA. The battery of testing included the following tests:

- Muscle Implantation Study in Rabbits – 4 weeks
- Maximization Sensitization
- Bacterial Reverse Mutation
- Systemic Toxicity in Mice
- USP Pyrogen Study
- Cytotoxicity
- Intracutaneous
- Chemical Characterization

The C-PTFE™ device is considered a >30 implantable device

Electrical safety and electromagnetic compatibility (EMC)

There are **no electrical components** in the C-PTFE™. No Electrical safety information is required for the safe functioning of this device.

Software Verification and Validation Testing

There is **no software** in the C-PTFE™ and the C-PTFE™ sutures requires no software to function. This section does not apply to this device.

Mechanical and acoustical testing

This section does not apply to this device.

Animal study

This section does not apply to this device.

Clinical Studies

This section does not apply to this device.

Summary

Based on the comparative testing between post sterile, aged, C-PTFE™ and MonoTex (predicate) currently in interstate commerce, the C-PTFE™ was found to have a safety and effectiveness profile that is similar to the predicate device.

Conclusions

The non-clinical data support the safety of the device and the sterilization validation demonstrate that the C-PTFE™ device should perform as intended in the specific use conditions. Based on the technological characteristics and non-clinical performance testing, the CP Medical C-PTFE™ Surgical Suture performs comparably the predicate device, MonoTex K140415, which is currently marketed for the same intended use.