May 10, 2018

RK Manufacturing Corporation
% Mr. John Gillespie
Consultant
Clover Medical, LLC
79 Haven St.
Dover, Massachusetts 02030

Re: K180625
Trade/Device Name: Rondek PGA Suture (Beige or Violet)
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: March 7, 2018
Received: March 9, 2018

Dear Mr. Gillespie:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K180625

Device Name
Rondek PGA Suture (Beige or Violet)

Indications for Use *(Describe)*
Rondek PGA suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and 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.

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510(k) Summary

Submitter:

510(k) Owner:
RK Manufacturing Corporation
34 Executive Drive, # 1
Danbury, CT 06810

Contact Person:
John Gillespie (Consultant)
Clover Medical LLC
79 Haven St.
Dover, MA 02030
www.CloverMedical.com

Date Prepared: May 8, 2018

Device Trade Name: Rondek PGA Suture

Common Name: Synthetic Absorbable Suture, PGA Suture

Classification:

Class: II
Panel: General and Plastic Surgery
Regulation: **878.4493** Absorbable Poly (Glycolide/L-Lactide) surgical suture
Product Code: **GAM** (Suture, Absorbable, Synthetic, Polyglycolic Acid)

Predicate Device: K992088 Bondek Plus Synthetic Absorbable Surgical Suture

Description of Device:

RK's Rondek PGA suture is a sterile, absorbable, braided suture composed of a homopolymer of glycolic acid and coated with a copolymer of Polycaprolactone and Polyglycolic acid.

Indications For Use:

Rondek PGA suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

Summary of Technological Characteristics vs. Predicate:
Rondek PGA suture has the same intended use, technology, and functional characteristics as its predicate Bondek® Plus Synthetic Absorbable Surgical Suture (K992088).

Performance Data
Performance data provided includes:

- USP Performance Testing
- Stability Evaluations
- EtO Residuals Testing
- LAL Pyrogen Testing
- Material Mediated Rabbit Pyrogen Testing
- Biocompatibility Testing
- Physico-Chemical Analysis

These tests support that the Rondek PGA suture meets relevant USP specifications and is equivalent to its predicate.

Conclusion
Based on the Indication for Use, technological characteristics, test data, and comparison to its predicate device we conclude that the Rondek PGA Suture has been shown to be as safe and effective as the predicate device.