February 28, 2020

Freudenberg Technology Innovation SE & Co. KG
% Sugato De
Vice President - Technical
Parexel International
4600 East-West Highway, Suite 350
Bethesda, Maryland 20814

Re: K192346
Trade/Device Name: scaffolene CL100 Bioresorbable Collagen Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: August 28, 2019
Received: August 29, 2019

Dear Sugato De:

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.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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,

Kimberly M. Ferlin, Ph.D.
Assistant Director (Acting)
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

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)*
K192346

Device Name
scaffolene® CL100 Bioresorbable Collagen Matrix

Indications for Use *(Describe)*
scaffolene® CL100 Bioresorbable Collagen Matrix is indicated for the management of full and partial thickness wounds in adult patients including:

Pressure ulcers
Diabetic ulcers
Ulcers caused by mixed vascular etiologies
Venous ulcers
Second degree burns
Donor and graft sites
Abrasions
Dehisced surgical wounds
Traumatic wounds healing by secondary intention

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 as required by 21 CFR 807.92(c)

scaffolene® CL100 Bioresorbable Collagen Matrix

Date Prepared: February 26, 2020

Submitter:
Freudenberg Technology Innovation SE & Co. KG
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Proprietary Name: scaffolene® CL100 Bioresorbable Collagen Matrix

Common Name: Collagen Wound Dressing

Classification: Unclassified, Preamendment
Product Code: KGN

Predicate Device: Covalon Technologies ColActive® Transfer (K123756)

Reason for Submission: New Device

Device Description

scaffolene® CL100 Bioresorbable Collagen Matrix is a collagen wound dressing provided sterile, which maintains a moist wound environment and supports exudate management. It can be cut to wound size, is a pliable absorbent dressing and can be adapted to irregular wound surfaces. scaffolene® CL100 Bioresorbable Collagen Matrix is resorbable and it can be left in place during secondary dressing changes.

scaffolene® CL100 Bioresorbable Collagen Matrix will typically resorb in about 1-3 days (shown in wound healing study in vivo), although this will be influenced by the patient's overall health. It is not necessary to remove the wound dressing.

Indications for Use

scaffolene® CL100 Bioresorbable Collagen Matrix is indicated for the management of full and partial thickness wounds in adult patients including:

- Pressure ulcers
- Diabetic ulcers
- Ulcers caused by mixed vascular etiologies

- Venous ulcers
- Second degree burns
- Donor and graft sites
- Abrasions
- Dehisced surgical wounds
- Traumatic wounds healing by secondary intention

Technological Characteristics

The indications for use for scaffolene® CL100 Bioresorbable Collagen Matrix are identical to those of the Covalon Technologies ColActive® Transfer (K123756). scaffolene® CL100 Bioresorbable Collagen Matrix has similar technological differences to those of the Covalon Technologies ColActive® Transfer (K123756), with differences in material characteristics, device design, resorption period, primary packaging, and device shelf-life.

Non-Clinical Data/Information

The following non-clinical data/information were provided to support a determination of substantial equivalence:

- Sterilization and Shelf-Life
  - Gamma Irradiation
  - Real-Time Aging to 1.5 Years
- Biocompatibility
  - Cytotoxicity
  - Sensitization
  - Intracutaneous Reactivity
  - Acute Systemic Toxicity
  - Materials Mediated Pyrogenicity
  - Subacute/Subchronic Toxicity
  - Genotoxicity
  - Implantation
  - Chemical Characterization and Toxicological Risk Assessment
- Animal-Derived Materials Safety Information
  - Animal Source
  - Virus Safety Risk Assessment
  - Collagen Characterization
- Performance Testing – Bench
  - Water Uptake
  - Protein Digestion
  - Unfoldability
  - Microscopic Appearance
  - Hot Water Stability
  - Conformability
- Performance Testing – Animal
  - Rat Wound Healing Study
  - Porcine Wound Healing Study

Conclusion

Non-clinical data demonstrate that scaffolene® CL100 Bioresorbable Collagen Matrix is as safe and as effective as the predicate device. In conclusion, scaffolene® CL100 Bioresorbable Collagen Matrix is substantially equivalent to the Covalon Technologies ColActive® Transfer (K123756).