December 15, 2022

PolyMedics Innovations GmbH
Kenneth Kleinhenz
Regulatory Affairs Consultant for Polymedics, Innovations, GmbH
Heerweg 15D
Denkendorf, 73770
Germany

Re: K170213
Trade/Device Name: SupraSDRM Biodegradable Matrix Wound Dressing
Regulatory Class: Unclassified
Product Code: QSZ

Dear Kenneth Kleinhenz:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 28, 2017. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSZ.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
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

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 28, 2017

Polymedics Innovations Gmbh
Mr. Kenneth Kleinhenz
Regulatory Affairs Consultant for Polymedics, Innovations, Gmbh
Heerweg 15d
Denkendorf, 73770 DE

Re: K170213
Trade/Device Name: SupraSDRM Biodegradable Matrix Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 14, 2017
Received: June 16, 2017

Dear Mr. Kleinhenz:

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 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, "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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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

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)*
K170213

Device Name
SurpaSDRM Biodegradable Matrix Wound Dressing

Indications for Use *(Describe)*

The SupraSDRM Biodegradable Matrix Wound Dressing is indicated for use in the management of:

- Partial and full thickness wounds
- Pressure (stage I and IV) and venous ulcers
- Ulcers caused by mixed vascular etiologies
- Venous stasis and diabetic ulcers
- 1st and 2nd degree burns
- Partial thickness burns
- Cuts and abrasions
- Acute wounds
- Trauma wounds
- Surgical wounds
- Superficial wounds
- Grafted wounds and donor sites

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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DATE OF PREPARATION: 26 June 2017

ADMINISTRATIVE INFORMATION

Manufacturer Name: PolyMedics Innovations, GmbH
Heerweg 15D
Denkendorf, Germany D-73770

Official Contact: Kenneth K. Kleinhenz
Regulatory Affairs
Telephone (858) 344-7143
Fax (858) 458-0994

DEVICE NAME

Classification Name: Dressing, Wound and Drug
Trade/Proprietary Name: SupraSDRM Biodegradable Matrix Wound Dressing

ESTABLISHMENT REGISTRATION NUMBER

3007710611

DEVICE CLASSIFICATION AND PRODUCT CODE

Wound and Drug Dressings are unclassified and have been assigned Product Code FRO.

INTENDED USE

The SupraSDRM Biodegradable Matrix Wound Dressing is indicated for use in the management of:

- Partial and full thickness wounds
- Pressure (stage I and IV) and venous ulcers
- Ulcers caused by mixed vascular etiologies
- Venous stasis and diabetic ulcers
- 1st and 2nd degree burns
- Partial thickness burns
- Cuts and abrasions
- Acute wounds
- Trauma wounds
- Surgical wounds
- Superficial wounds
- Grafted wounds and donor sites

DEVICE DESCRIPTION

The SupraSDRM Biodegradable Matrix Wound Dressing is a tri-polymer, Biodegradable dermal covering that is provided in a flat sheet. The SupraSDRM Biodegradable Matrix Wound Dressing can be cut with scissors to the desired shape and size. The SupraSDRM Biodegradable Matrix Wound Dressing is fully malleable at room temperature and becomes more pliable at body temperature and thus can be conformed three dimensionally to most any anatomical orientation. The SupraSDRM Biodegradable Matrix Wound Dressing can be used either alone or in conjunction with a petroleum jelly and/or gauze wound and burn dressing which can also serve to further secure the SupraSDRM Biodegradable Matrix Wound Dressing and prevent dislocation. The PolyMedics Innovations (PMI) SupraSDRM Biodegradable Matrix Wound Dressing is provided in various shapes such as rectangles, ovals, and circles and will be provided in other shapes and sizes as needed for particular wound and burn-care applications. The PolyMedics Innovations (PMI) SupraSDRM Biodegradable Matrix Wound Dressing is provided in sheets of 50mm x 50mm to 180mm to 230mm and will be provided in other shapes and sizes as needed for particular burn and wound-care applications. The thickness of the PolyMedics Innovations (PMI) SupraSDRM Biodegradable Matrix Wound Dressing ranges from 1,500µm to 2,100µm according to the region to be treated. The PolyMedics Innovations (PMI) SupraSDRM Biodegradable Matrix Wound Dressing is provided in solid sheets that contain micropores that range in size from 13µm to 300µm.

Material Composition

The SupraSDRM Biodegradable Matrix Wound Dressing is fabricated from a tri-polymer of polylactide, trimethylene carbonate, ε-caprolactone and polyvinyl alcohol.

In Vitro Testing

Mechanical tensile strength testing and inherent viscosity testing were performed on the PolyMedics Innovations (PMI) SupraSDRM Biodegradable Matrix Wound Dressing and compared to the predicate device with samples exposed to in vitro saline conditions of 37°C at various time periods.

Biocompatibility testing of the SupraSDRM Biodegradable Matrix Wound Dressing was performed according to ISO 10993-5 - Biological Evaluation of Medical Devices – Part 5: Tests for in Vitro Cytotoxicity and ISO 10993-10 - Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization.

Sterilization validations were performed against EN ISO 11137-1: Sterilization of Health Care Products – Radiation – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices.

Package seals were evaluated for seal integrity and seal strength against ANSI/AAMI/ISO 11607–1 Packaging for Terminally Sterilized Medical Devices Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging, and ANSI/AAMI/ISO 11607–2 Packaging for Terminally Sterilized Medical Devices Part 2: Validation Requirements for Forming, Sealing and Assembly Process.

The following chemical and physical characteristics of the SupraSDRM Biodegradable Matrix Wound Dressing and the predicate device were compared: material composition, percentage of DL-lactide, percentage of caprolactone, percentage of trimethylene carbonate, inherent viscosity, glass transition temperature, porosity, product thickness, and manufacturing process.

Stability of the SupraSDRM Biodegradable Matrix Wound Dressing was evaluated against the following tests: inherent viscosity, porosity, product thickness, glass transition temperature, residual monomer, and residual excipients.

EQUIVALENCE TO MARKETED PRODUCT

The PolyMedics Innovations (PMI) SupraSDRM Biodegradable Matrix Wound Dressing shares indications and design principles with the following predicate device and reference devices which have been determined by FDA to be substantially equivalent to pre-amendment devices: Suprathel Wound and Burn Dressing (K090160) predicate device and the Integra LifeSciences Bilayer Matrix Wound Dressing (K021792) reference device, and Progressive Woundcare Technologies Iodophor Foam Dressing (K122634) reference device; Unclassified medical devices that were cleared for marketing in the United States under K090160, K021792 and K122634 respectively**.**

Indications for Use

The SupraSDRM Biodegradable Matrix Wound Dressing and the Suprathel Wound and Burn Dressing (K090160), Integra LifeSciences Bilayer Matrix Wound Dressing (K021792), and the Progressive Woundcare Technologies Iodophor Foam Dressing (K122634) predicate and reference devices are substantially equivalent with respect to their indications for use as they are all indicated for the same uses as temporary dermal coverings of minor burns and various dermal wounds such as: diabetic ulcers, pressure ulcers, venous stasis ulcers, burns, traumatic wounds, surgical wounds, etc.

Design and Materials

The design and materials of the PolyMedics Innovations (PMI) SupraSDRM Biodegradable Matrix Wound Dressing, the predicate device [Suprathel Wound and Burn Dressing (K090160)] and the reference devices [Integra LifeSciences Bilayer Matrix Wound Dressing (K021792), and Progressive Woundcare Technologies Iodophor Foam Dressing (K122634)] are substantially equivalent as they are all sterile, single use, flat, thin, rectangular Biodegradable sheets with design characteristics of being flexible and semi-rigid devices that can be contoured in situ and cut to shape with surgical scissors.

The PolyMedics Innovations (PMI) SupraSDRM Biodegradable Matrix Wound Dressing and the predicate devices [Suprathel Wound and Burn Dressing (K090160)] and reference devices [Integra LifeSciences Bilayer Matrix Wound Dressing (K021792), and Progressive Woundcare Technologies Iodophor Foam Dressing (K122634)] are substantially equivalent as they all have a thickness of 50µm – 2100µm and range in size from 50mm x 50mm to 180mm x 230mm.

The PolyMedics Innovations (PMI) SupraSDRM Biodegradable Matrix Wound Dressing and the predicate device [Suprathel Wound and Burn Dressing (K090160)] and reference devices [Integra LifeSciences Bilayer Matrix Wound Dressing (K021792)] are substantially equivalent as they are all porous materials with pores that range in size from 5µm – 300µm and have a porosity that range from 85 – 98%.

The PolyMedics Innovations (PMI) SupraSDRM Biodegradable Matrix Wound Dressing and the predicate device [Suprathel Wound and Burn Dressing (K090160)] and the reference device [Integra LifeSciences Bilayer Matrix Wound Dressing (K021792)] are substantially equivalent as they all have a mass per unit area of 45 – 150 g/m^2.

The PolyMedics Innovations (PMI) SupraSDRM Biodegradable Matrix Wound Dressing and the Suprathel Wound and Burn Dressing (K090160) predicate device are substantially equivalent as they are both fabricated from the same poly(DL-lactide-co-trimethylene carbonate-co-ε-caprolactone) in the same ratio.

The PolyMedics Innovations (PMI) SupraSDRM Biodegradable Matrix Wound Dressing and the Woundcare Technologies Iodophor Foam Dressing (K122634) reference device are substantially equivalent as they are both fabricated from the same polyvinyl alcohol material.