December 15, 2022

PolyNovo Biomaterials Pty Ltd.
Ms. Sue Cho
Regulatory Affairs Manager
Unit 2, 320 Lorimer Street
Port Melbourne, Victoria 3207
Australia

Re: K172140
Trade/Device Name: NovoSorb™ BTM Wound Dressing (2cm x 2cm), NovoSorb™ BTM Wound Dressing (10cm x 10cm), NovoSorb™ BTM Wound Dressing (10cm x 20cm), NovoSorb™ BTM Wound Dressing (20cm x 40cm)
Regulatory Class: Unclassified
Product Code: QSZ

Dear Ms. Sue Cho:

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 August 11, 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

August 11, 2017

PolyNovo Biomaterials Pty Ltd
Ms. Sue Cho
Regulatory Affairs Manager
Unit 2, 320 Lorimer Street
Port Melbourne, Victoria 3207 Australia

Re: K172140
Trade/Device Name: NovoSorb BTM Wound Dressing (2cm x 2cm), NovoSorb BTM Wound Dressing (10cm x 10cm), NovoSorb BTM Wound Dressing (10cm x 20cm), NovoSorb BTM Wound Dressing (20cm x 40cm)
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 13, 2017
Received: July 17, 2017

Dear Ms. Cho:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172140

Device Name

NovoSorb BTM Wound Dressing

Indications for Use *(Describe)*

The NovoSorb™ BTM Wound Dressing is indicated for use in the management of wounds including: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic and vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. The device is for single use only.

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.

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Office of Chief Information Officer
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"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."

Section 6. 510(k) Summary

Date Prepared: 13 July 2017

APPLICANT INFORMATION:

Applicant/Submitter: PolyNovo Biomaterials Pty Ltd
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Victoria, Australia 3207

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Establishment Registration Number: 3007886187

Contact Person: Sue Cho
Regulatory Affairs Manager
Phone: +61 3 8681 4060
Email: sue.c@polynovo.com

Alternate Contact Person: Joseph DePaolo
Director of Regulatory Affairs
Phone: 508 631 8436
Email: joe.d@polynovo.com

Ivan Jasenko
Regulatory & Quality Systems Manager
Phone: +61 3 8681 4070
Email: ivan.j@polynovo.com

SUBJECT DEVICE INFORMATION:

Trade Name: NovoSorb™ BTM Wound Dressing

Device Common Name: Wound Dressing

Classification Name: Dressing, Wound, Drug

Product Code: FRO

Product Classification: Unclassified

PREDICATE DEVICE INFORMATION:

Predicate Device: BTM Wound Dressing, K142879

6.1 Device Description

The NovoSorb™ BTM Wound Dressing device is a 2mm thick, porous, white biodegradable polyurethane foam bonded with a polyurethane adhesive layer to a fenestrated one-sided transparent sealing membrane. The sealing membrane is designed to physiologically close the wound limiting evaporative water loss during integration of the foam. The adhesive layer and sealing membrane are to be removed and discarded when appropriate leaving only the foam layer to biodegrade in patients.

NovoSorb™ BTM Wound Dressing device is supplied in various sizes, ranging from 4cm^2 to 800cm^2. The NovoSorb™ BTM Wound Dressing is a single use, terminally sterilized device, individually packed in a transparent polymer pouch enclosed in a white aluminized pouch contained in a cardboard envelope.

6.2 Indications for Use

The NovoSorb™ BTM Wound Dressing device is indicated for use in the management of wounds including: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic and vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. The device is for single use only.

6.3 Technological Characteristics Comparison

The NovoSorb™ BTM Wound Dressing device is a modification of the existing predicate device BTM Wound Dressing, K142879. The predicate and the subject device have the same technological characteristics, however the subject device is supplied to the user fenestrated, thereby removing the need for users to manually fenestrate the device prior to use.

6.4 Non-Clinical Tests

Mechanical testing was performed on the subject device. Results of the tests demonstrate that the mechanical properties of the subject device meet the device requirements and that the subject device is substantially equivalent to the predicate device.

6.5 Clinical Tests

No clinical tests were performed; determination of substantial equivalence was not based on an evaluation of clinical performance data.

6.7 Conclusion

PolyNovo believes the modified NovoSorb BTM Wound Dressing device is substantially equivalent to the legally marketed predicate device, BTM Wound Dressing (K142879), because its design and materials used, methods of operation and technological characteristics are either identical or substantially equivalent to the existing marketed predicate. It has the same intended use and maintains the same safety and effectiveness as its premarket cleared predicate device. Any differences that exist between the devices do not affect the intended use or alter the fundamental scientific technology of the device.