December 15, 2022

PolyNovo Biomaterials Pty Ltd.
Ms. Ivy Cheng
Regulatory Affairs and Clinical Compliance Manager
Unit 2, 320 Lorimer Street
Port Melbourne, Victoria 3207
Australia

Re: K142879
Trade/Device Name: BTM Wound Dressing
Regulatory Class: Unclassified
Product Code: QSZ

Dear Ms. Ivy Cheng:

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 December 23, 2015. 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

December 23, 2015

PolyNovo Biomaterials Pty Ltd.
Ms. Ivy Cheng
Regulatory Affairs and Clinical Compliance Manager
UNIT 2, 320 LORIMER STREET
Port Melbourne, 3207
Victoria, Australia

Re: K142879
Trade/Device Name: BTM Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 18, 2015
Received: December 18, 2015

Dear Ms. Cheng:

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" (21CFR 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 yours,

Binita S. Ashar -S

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)*
K142879

Device Name
BTM Wound Dressing

Indications for Use *(Describe)*

The BTM Wound Dressing is indicated for 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 intended for one-time use.

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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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."

5. 510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the BTM Wound dressing is provided below.

Device Common Name:	Dressing, Wound
Device Proprietary Name:	BTM Wound dressing
510(k) Number:	K142879
Submitter:	PolyNovo Biomaterials Pty Limited Unit 2 /320 Lorimer Street Port Melbourne, VIC 3207
Contact:	**Ivy Cheng**, Regulatory Affairs and Clinical Compliance Manager PolyNovo Biomaterials Pty Ltd Unit 2, 320 Lorimer Street Port Melbourne 3207, Victoria, Australia Phone: +61 3 8681 4060 Fax: +61 3 8681 4099 Email: ivy.c@polynovo.com
Alternate Contact:	**Tim Moore**, Principal Scientist PolyNovo Biomaterials Pty Ltd Unit 2, 320 Lorimer Street Port Melbourne 3207, Victoria, Australia Phone: +61 3 8681 4086 Fax: +61 3 8681 4099 Email: tim.m@polynovo.com
Date Prepared:	**September 30, 2014**
Classification Regulation:	Unclassified
Panel:	General & Plastic Surgery
Product Code:	FRO
Predicate Devices:	Suprathel Wound and Burn Dressing (K090160) Bilayer Matrix Wound Dressing (K021792)

Indications for Use:

The BTM Wound dressing is indicated for 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 intended for one-time use.

Device Description:

The BTM Wound dressing is a biodegradable dermal covering that is comprised of three layers:

Biodegradable Layer:

1. Foam - A wound-facing, 2mm thick, white, open cell degradable foam with a high degree of porosity (>90%) designed to subsequently biodegrade. The foam is a biocompatible, biodegradable polyurethane material.

Removable Layer:

2. Adhesive (bonding) layer - A polyurethane bonding layer which bonds the Foam and Sealing Membrane together.
3. Sealing Membrane - A transparent polyurethane membrane designed to physiologically close the wound and limit evaporative water loss. The sealing membrane is designed to remain attached to the dermal foam, if required, for at least 30 days in vivo.

The BTM Wound dressing is supplied in various sizes, ranging from 10cm x 10cm, up to 20cm x 40cm. The dressings are single use, terminally sterilized devices, individually packed in a polymer pouch within an aluminized envelope.

Patient biopsy data has shown that BTM Wound dressing degrades by 10 - 12 months. In vitro degradation data indicates that the BTM Wound dressing disintegrates by approximately 10 months. However, actual degradation time in patients may vary depending on a number of factors including but not limited to anatomical location, age, and health status.

Comparison of Indications for Use:

BTM Wound dressing, shares indications for use principles with the predicate devices, Suprathel Wound and burn dressing (Suprathel) and Integra's Bilayer Matrix Wound Dressing (Integra) as both are all indicated for use in partial and full thickness wound management. The proposed Indication for Use for BTM Wound dressing exactly matches that of the Integra predicate device.

Comparison of Design and Materials:

BTM Wound dressing is composed of a synthetic foam with a polyurethane sealing membrane, while the Integra predicate device is composed of collagen foam with a silicone sealing membrane. The Suprathel predicate device is comprised of polyester-carbonate which is a similar synthetic foam material as the BTM Wound dressing but without a sealing membrane. BTM Wound dressing contains a skin-facing layer that is designed to biodegrade in the wound which is substantially equivalent to both predicates.

The average porosity of BTM Wound dressing was measured to be 188µm which is

substantially equivalent to the Integra predicate device.

Mechanical testing was performed on the BTM Wound dressing and showed improved tensile strength and elongation at break compared to Suprathel predicate device. In addition, BTM Wound dressing demonstrated superior cyclic testing robustness in comparison to Suprathel predicate device.

The average thickness of BTM Wound dressing was measured to be approximately 2mm. The average thickness of Suprathel predicate device was measured to be approximately 160 μm and the thickness of the Integra predicate device is 2 mm, which is equivalent to that of the BTM Wound dressing. Therefore, BTM Wound dressing is substantially equivalent to the predicate devices.

BTM Wound dressing is radiation sterilized and is intended for single use only which is substantially equivalent to both predicate devices.

Non Clinical Data:

Biocompatibility studies have demonstrated the BTM Wound dressing to be non-cytotoxic, non-irritating and non-sensitizing. In addition, in vitro chemical analyses, degradation and pH studies; and toxicological risk analysis support the safety of BTM Wound dressing.

Clinical Evidence:

Clinical studies were conducted with respect to Biocompatibility, substantial equivalence and comparison to the predicate devices.

In clinical studies in 14 patients requiring free flap surgery, 2 adverse events were reported that were deemed "possibly related" to the BTM by the investigators. These events were graft failure (n = 1) and hematoma (n = 1). The events were reported at similar frequencies in similar patient studies reported in the literature (Moazzam et al., 2003: 15%; and Lutz et al., 1999: 6.3%).

In patients undergoing BTM application at donor harvest sites, recipient site complications were reported. These complications occurred at a similar frequency to those reported in the literature for patients undergoing similar free tissue transfer procedures.

In some patients treated with BTM, elevations in liver function tests (LFTs) were reported. These elevations were reported at similar frequencies in a control cohort of patients undergoing similar procedures requiring long duration anesthesia. While the elevations proved to be transient in patients for which longer follow-up occurred, levels remained elevated in patients with shorter follow-up durations. The investigators reported that the elevated LFTs were unlikely to be related to the BTM and were likely to be a side effect of long-duration anesthesia. However, the exact cause of the elevated LFT and their resolution in the patients with only short term follow-up has not been established. None of the patients were treated for abnormal liver function during the study.

Conclusion of Substantial Equivalence

The bench testing, biocompatibility, non clinical and clinical evidence provided supports the safety and effectiveness of BTM Wound dressing for the proposed indications for use, and is, with respect to intended use and technological characteristics substantially equivalent to the predicate devices.