June 20, 2025

PolyNovo Biomaterials Pty Ltd
Shruti Dave
Regualtory Affairs Project Manager
2/320 Lorimer Street
Port Melbourne
Melbourne, VIC 3207
Australia

Re: K251567
Trade/Device Name: NovoSorb BTM
Regulatory Class: Unclassified
Product Code: QSZ
Dated: May 6, 2025
Received: May 22, 2025

Dear Shruti Dave:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251567

Device Name
NovoSorb® BTM

Indications for Use *(Describe)*

NovoSorb BTM 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.

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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510(k) Summary

Date Summary Prepared: 20 June 2025

APPLICANT INFORMATION:

Applicant/Submitter: PolyNovo Biomaterials Pty Ltd
2/320 Lorimer Street, Port Melbourne
VIC 3207 Australia

Establishment Registration Number: 3007886187

Contact Person: Ms. Shruti Dave
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Alternate Contact Person: Mr. Joeseph DePaolo
Senior Director – Regulatory Affairs
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SUBJECT DEVICE IFORMATION:

Trade Name:	NovoSorb® BTM
Device Common Name:	Wound Dressing
Classification Name:	Absorbable Synthetic Wound Dressing
Product code:	QSZ
Product Classification:	Unclassified

PREDICATE DEVICE INFORMATION:

Predicate Device:	NovoSorb BTM, K172140
Reference Device:	NovoSorb MTX, K242149

DEVICE DESCRIPTION:

The NovoSorb BTM device has been modified to expand the available thickness of the foam component from 2 mm to 2-6 mm. Sizes are limited to a maximum volume of 160 cm^3. The device continues to be a porous, biodegradable, polyurethane foam, adhered to a fenestrated transparent sealing membrane. The sealing membrane is designed to physiologically close the wound limiting evaporative moisture loss during integration of the foam. The sealing membrane is to be removed and discarded when appropriate, leaving only the foam layer to biodegrade in patients.

NovoSorb BTM is a terminally sterilized, single use device intended for deep partial and full thickness wounds. Each NovoSorb BTM is packed in a transparent polymer pouch, enclosed in an aluminized pouch. A product label is placed on the pouch. The aluminized pouch

together with an instruction for use is individually packaged in a cardboard envelope and a product label is placed on the envelope.

INDICATIONS FOR USE

The NovoSorb BTM 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.

TECHNOLOGICAL CHARACTERISTICS

The proposed NovoSorb BTM device is the same as the previously cleared predicate NovoSorb BTM (K172140) in terms of physical and material properties, maximum volume of 160 cm^3 of the foam, manufacturing, indications for use, environment of use, packaging, shelf life, and sterilization. Like the predicate device, the proposed device consists of a fenestrated sealing membrane adhered to the foam; constructed from the same synthetic biodegradable polyurethane material using the same manufacturing process. In both the proposed device and the predicate device, the foam provides a scaffold for cellular infiltration and vascularization. The foam permits the ingress of cells and soft tissue formation in the defect space/wound bed.

The properties of the foam component, including average pore size, porosity, and density, remain unchanged compared to both predicate devices. Additionally, the proposed device is sterilized using gamma radiation at a dose of 25–40 kGy, achieving a sterility assurance level (SAL) of 10^{-6}, which is consistent with both predicate devices. The proposed NovoSorb BTM device also offers the same range of foam thicknesses (2 mm to 6 mm) as the secondary predicate, NovoSorb MTX (K242149), ensuring similarity in structural characteristics.

The subject device has the same characteristics as the predicate device as follows:

Characteristic	NovoSorb BTM (subject device)	NovoSorb BTM K173544 (predicate device)	NovoSorb MTX K242149 (reference predicate)	Comparison
Product Code	QSZ	QSZ	QSZ	Same
Device Class	Unclassified	Unclassified	Unclassified	Same
Indication for Use	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-	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-	Indicated for use in the management of wounds including: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic and vascular ulcers, tunneled/undermined wounds, surgical wounds (donor	Same as Predicate Device

Characteristic	NovoSorb BTM (subject device)	NovoSorb BTM K173544 (predicate device)	NovoSorb MTX K242149 (reference predicate)	Comparison
	laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds.	laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds.	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.	
Materials of Construction	Polyurethane	Polyurethane	Polyurethane	Same
Physical Structure	Foam with fenestrated sealing membrane	Foam with fenestrated sealing membrane	Foam only	Same as Predicate Device
Size Range	L x W x T limited to a volume of 160 cm^3	L x W x T limited to a volume of 160 cm^3	L x W x T limited to a volume of 160 cm^3	Same
Thickness	2-6 mm	2 mm	2-6 mm	Same as Reference Device
Sealing Membrane	Yes	Yes	No	Same as Predicate Device
Packaging	polymer pouch within an aluminized envelope	polymer pouch within an aluminized envelope	polymer pouch within an aluminized envelope	Same
Sterilization	Gamma	Gamma	Gamma	Same
Single Use	Yes	Yes	Yes	Same

NON-CLINICAL TESTS

Verification performance testing demonstrates that the proposed NovoSorb BTM will consistently meet established functional and performance requirements. These requirements include physical characteristics, mechanical strength, and durability. The same testing protocol used in the predicate was utilized to conduct this verification bench testing. 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.

CLINICAL TESTS

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

CONCLUSION

PolyNovo believes the modified NovoSorb BTM device is substantially equivalent to the legally marketed predicate devices NovoSorb BTM (K172140) and NovoSorb MTX

(K242149), because no differences in technological characteristics exist between different foam thicknesses as there is no change to the foam density for different foam thicknesses. It has the same intended use and maintains the same safety and effectiveness as its previously cleared predicate devices. Any difference that exists between the devices do not affect the intended use or alter the fundamental scientific technology of the device.