March 5, 2025

PolyNovo Biomaterials Pty Ltd
Tarun Nekkenti
Regulatory Affairs Project Manager
2/320 Lorimer St
Port Melbourne
Melbourne, Victoria 3207
Australia

Re: K242149
Trade/Device Name: NovoSorb® MTX
Regulatory Class: Unclassified
Product Code: QSZ
Dated: January 30, 2025
Received: January 30, 2025

Dear Tarun Nekkenti:

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.

Submission Number *(if known)*

K242149

Device Name

NovoSorb® MTX

Indications for Use *(Describe)*

NovoSorb® MTX is indicated for 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 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 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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510(k) Summary

Date Prepared: 04 March 2025

510(k) No: K242149

APPLICANT INFORMATION:

Applicant/Submitter: PolyNovo Biomaterials Pty Ltd
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Establishment Registration Number: 3007886187

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Director of Regulatory Affairs
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SUBJECT DEVICE INFORMATION:

Trade Name: NovoSorb® MTX

Device Common Name: Wound Dressing

Classification Name: Absorbable Synthetic Wound Dressing

Product Code: QSZ

Product Classification: Unclassified

PREDICATE DEVICE INFORMATION:

Predicate Device: NovoSorb® Matrix, K221686

Reference Device: Restrata®, K193583

Device Description

NovoSorb® MTX is a fully synthetic biodegradable device that is composed of a single foam layer. The foam is a 2-6 mm thick, white, open cell degradable foam with a high degree of porosity (>90%) providing a scaffold for dermal tissue integration. NovoSorb® MTX will be supplied in sizes ranging from 4 cm^2 to 800 cm^2 with a maximum volume of 160 cm^3.

NovoSorb® MTX is a terminally sterilized, single use device intended for deep partial and full thickness wounds. It is intended for use by qualified healthcare professionals in a hospital/clinical environment and is not intended for use at home.

Each NovoSorb® MTX 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

NovoSorb® MTX is indicated for 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 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 single use only.

Technological Characteristics Comparison

The proposed NovoSorb® MTX device is the same as the predicate NovoSorb® Matrix device in principle of operation, physical and material properties, packaging, sterilization method, sterility assurance level (SAL), and shelf life. The foam of the proposed device is constructed from the same synthetic biodegradable polyurethane material and in the same manner as the predicate device. The properties of the foam component with respect to the average pore size, porosity and density remain the same as the predicate device. 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 subject device also has an updated indication of use to include tunneled/undermined wounds. The subject device and the reference predicate device Restrata® have similar characteristics as absorbable, synthetic, sterile, single use devices intended for use in local management of wounds that provide a moist environment for the body’s natural healing process to occur. Both are designed to have a structure with high porosity intended to provide a scaffold for cellular infiltration and vascularization before completely degrading via hydrolysis, and both the devices permit the ingress of cells and soft tissue formation in the defect space / wound bed.

The inclusion of tunneled/undermined wounds within the indications for use of the subject device does not alter the intended use, the mechanism of action or the principle of operation when compared to the reference predicate device and the predicate device. This addition is consistent with the subject device's established function and intended use and does not introduce any new or significant differences.

Non-Clinical Tests

Verification performance testing demonstrates that the proposed NovoSorb® MTX 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.

An accelerated hydrolytic degradation study designed to evaluate the relative rate of degradation of the subject device (6 mm) compared to the predicate device (2 mm) was performed based on ISO 10993 Part 13: Identification and quantification of degradation products from polymeric medical devices.

NovoSorb® MTX is categorized as a surface device for long term (>30 days) contact with breach and/or compromised skin surfaces. Biocompatibility risk assessment was conducted in accordance with ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. The following biocompatibility endpoints were leveraged from the predicate 2-mm device (K142879), which shares the same synthetic biodegradable polyurethane material and manufacturing process as the 4-mm and 6-mm dressings: Cytotoxicity, Sensitization, Irritation, Material mediate pyrogenicity, Systemic toxicity, Genotoxicity, and Carcinogenicity. Implantation (local tissue response) was addressed *in vivo* by comparing the local tissue response of NovoSorb® MTX 4-mm and 6-mm dressings to the predicate dressing. The findings of these tests demonstrated that the 4-mm and 6-mm dressings performed similarly to the predicate 2-mm dressing and were characterized by a similar tissue response.

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 proposed NovoSorb® MTX is substantially equivalent to the predicate device NovoSorb® Matrix, K221686 based on the evaluation of intended use, biocompatibility, performance characteristics and performance testing.