June 17, 2026

Oneness Biotech Co., Ltd.
Angel Hsieh
Regulatory Affairs Manager
35f, #66, # 66, Sec. 1, Zhongxiao W. Rd., Zhongzheng Dist., Taipei City
Taipei, 100
Taiwan

Re: K261638
Trade/Device Name: Bonvadis®
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 18, 2026
Received: May 18, 2026

Dear Angel Hsieh:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

MUSTAFA A. MAZHER -S

For Yu-Chieh Chiu
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)*
K261638

Device Name
Bonvadis®

Indications for Use *(Describe)*
Under the direction of a healthcare professional, the Rx product is indicated for the management of partial and full thickness wounds, post-surgical wounds, 1st and superficial 2nd degree burns, diabetic foot ulcers, venous stasis ulcers, and pressure ulcers.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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."

510(k) Summary

General Information

Preparation Date:	May 18, 2026
510(k) Number:	K261638
Applicant :	Oneness Biotech Co., Ltd. 35F., No. 66, Sec. 1, Zhongxiao W. Rd., Zhongzheng Dist., Taipei City 100, Taiwan, R.O.C. Tel: +886 2 27031098
Contact Person:	Angel Hsieh Regulatory Affairs Manager md.regulatory@onenessbio.com.tw

Device Information

Device Name: Bonvadis®
Classification Name: Dressing, Wound, Drug
Common Name: Wound Dressing
Product Codes: FRO
Regulation Number: Unclassified

Predicate Devices

Bonvadis® Topical Cream cleared under K251093 on June 9, 2025.

Device Description

Bonvadis® is a non-occlusive, non-sterile, preserved, semi-viscous topical matrix formulation for prescription use, for single use application directly to the wound bed. Bonvadis® contains methyl and propyl parabens which act as preservatives to inhibit the growth of microorganisms within the product before opening.

Ingredients: Purified water, liquid petrolatum, white petrolatum, propylene glycol, cetyl stearyl alcohol, span 60, tween 60, *Centella Asiatica* extract, Mexican Mint extract, Methyl Paraben, and Propyl Paraben.

Indications for Use

Under the direction of a healthcare professional, the Rx product is indicated for the management of partial and full thickness wounds, post-surgical wounds, 1st and superficial 2nd degree burns, diabetic foot ulcers, venous stasis ulcers, and pressure ulcers.

Comparison of Technological Characteristics

The subject device is substantially equivalent to its predicate Bonvadis® (K251093). **Table 1** compares the subject and predicate devices.

The subject device is unchanged from the legally marketed predicate Bonvadis® (K251093) in its intended use, formulation, and design, except for the addition of a 3g package size.

There are no changes to the materials of aluminum tube and screw cap, nor other design aspects. The aluminum tube dimensions are modified only to accommodate for the specific filling volume.

There is no change to the intended use of the subject device, and the modifications do not raise new safety and effectiveness concerns. Substantial equivalence has been demonstrated through conformity to recognized standards and design verification and validation evaluation.

Table 1 – Comparison of Subject and Predicate Devices

Comparison Feature	**Subject Device Bonvadis®**	**Predicate Device Bonvadis®**
510(k) Number	K261638	K251093
Product Code	FRO, Dressing, Wound, Drug	FRO, Dressing, Wound, Drug
Product Classification	Unclassified	Unclassified
Intended Use	A topical matrix formulation that maintains a wound environment.	Identical as subject device
Indications for Use	Under the direction of a healthcare professional, the Rx product is indicated for the management of partial and full thickness wounds, post-surgical wounds, 1st and superficial 2nd degree burns, diabetic foot ulcers, venous stasis ulcers, and pressure ulcers.	Identical as subject device
Mechanism of Action	The semi-solid topical matrix formulation provides a moist wound environment that is conducive to healing process.	Identical as subject device
Sterility Claim	Non-sterile	Identical as subject device
Delivery System	Topical use on the surface of the wound	Identical as subject device
How Supplied	3 g	15 g
Storage Condition	15℃ ~ 30℃	Identical as subject device

Standard and Testing

There are no changes to the following non-clinical evaluations: Shelf-life stability, In use stability, Transepidermal water loss (TEWL), Water retention capacity, Biocompatibility, Toxicological risk assessment, Usability, and Transportation testing. These are supported by a verification and validation evaluation summary, confirming that the safety and effectiveness remain substantially equivalent to the predicate device. Additionally, pH value, Microbial limit per USP<61> and USP<62>, Weight, Viscosity, Water loss rate, and Endotoxin testing were conducted for the subject device to demonstrate adherence to the identical performance specifications of the predicate.

Substantial Equivalence Conclusion

The subject device Bonvadis® is substantially equivalent to the previous cleared Bonvadis® (K251093) with the change described within this submission. Bonvadis® has demonstrated that the device is as safe, effective, and performs as well as the predicate devices.