June 7, 2024

StemCyte Inc.
Angel Hsieh
Regulatory Affairs Manager
13800 Live Oak Avenue
Baldwin Park, California 91706

Re: K232655
Trade/Device Name: Bonvadis®
Regulatory Class: Unclassified
Product Code: FRO

Dear Angel Hsieh:

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 May 22, 2024. Specifically, FDA is updating this SE Letter as an administrative correction to the clearance letter, as it was not signed by/for the Assistant Director.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Yu-Chieh Chiu, Ph.D., OHT4: Office of Surgical and Infection Control Devices 301-796-6196, yu-chieh.chiu@fda.hhs.gov.

Sincerely,

Mustafa A. Mazher -S

for Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and 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

May 22, 2024

StemCyte Inc.
Angel Hsieh
Regulatory Affairs Manager
13800 Live Oak Avenue
Baldwin Park, California 91706

Re: K232655
Trade/Device Name: Bonvadis®
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 22, 2024
Received: April 22, 2024

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 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.

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,

for Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232655

Device Name
Bonvadis®

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

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

1. General Information

FDA Submission Document No: K232655
510(k) Submitter: StemCyte Inc.
Address: 13800 Live Oak Avenue, Baldwin Park, CA 91706, USA
Tel: +1 626 6462457
Submission Contact Person: Angel Hsieh
angel.hsieh@stemcyte.com.tw

May. 21, 2024

2. Device Information

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

3. Predicate Devices

Bonvadis Topical Cream cleared under K212554 on Aug. 19, 2022.
BIAFINE Topical Cream cleared under K173549 on Aug.13, 2018.

4. Product Description

Bonvadis® is a non-sterile water based, preserved, semi-viscous formulation, for prescription use.
Bonvadis® contains methyl and propyl parabens which act as preservatives to inhibit the growth of microorganisms within the product before opening and between uses.
Bonvadis® is multiple use and supplied in a 15 g aluminum tube.
The formulation is to maintain a moist wound environment, the moist wound environment being conducive for wound healing.

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.

5. Indications for Use

Under the direction of a healthcare professional, the Rx product is indicated for the management of partial thickness wounds, closed post-surgical wounds, and 1st and superficial 2nd degree burns.

6. Summary of Technological Characteristics

Bonvadis® and BIAFINE products are non-sterile water based, preserved, semi-viscous formulations which have similar indications for use and storage. All three products retain a neutral pH, and are used topically in addition both contain humectant and emollient components which donate moisture to the skin.

	Subject Device	Predicate Device	Predicate Device
Characteristic	K232655	K212554	K173549
Intended Use	A wound dressing which creates a moist wound environment necessary to the healing process	Identical as subject device	Identical as subject device
Rx Indications for Use	Under the direction of a healthcare professional, the Rx product is indicated for the management of partial thickness wounds, closed post-surgical wounds, and 1st and superficial 2nd degree burns.	-	BIAFINE is indicated for the management of full thickness wounds, pressure sores, dermal ulcers including lower leg ulcers, radiation dermatitis, donor sites and 2nd degree burns. BIAFINE may also be used for relief of itch, pain and burning from minor skin irritations, lacerations, abrasions and minor burns.
OTC indications for Use	-	For Over-the-Counter Use: Bonvadis® is indicated for the management of minor skin lacerations, abrasions, cuts, and minor burns.	BIAFINE is indicated for management of superficial wounds such as minor cuts, minor scrapes, minor irritations, minor abrasions, minor blisters, 1st degree burns including sunburns, minor skin irritations following post non ablative laser therapy procedures, microdermabrasion therapy or superficial chemical peels.

			BIAFINE may also be used for relief of itch, pain and burning from minor skin irritations, lacerations, abrasions and minor burns.
Sterility Claim	Non-sterile	Identical as subject device	Identical as subject device
Mechanism of Action	Provides a moist wound environment that is conducive to healing process	Identical as subject device	Identical as subject device
Delivery System	Topical use on the surface of the wound	Identical as subject device	Identical as subject device

7. Performance Data

   Non-clinical tests including Shelf-life stability, In use stability, Transepidermal water loss (TEWL), Water retention capacity test, Biocompatibility tests and toxicological risk assessment, usability and Transportation tests were performed to support the safety and effectiveness to be substantial equivalence with predicate devices. pH value, Microbial limit per USP<61> and USP<62>, Weight, Viscosity, Water loss rate, and Endotoxin testing were conducted to support the Shelf life and In-Use study data and preservative efficacy as per USP<51> and the results meet the criteria as per USP<51>.

8. Conclusion

   In accordance with non-clinical test results, including shelf-life stability, in-use stability, TEWL, water retention capacity, biocompatibility evaluation, toxicological risk assessment, usability, transportation, quality inspections, and preservative effectiveness tests, Bonvadis has demonstrated that the device is as safe, effective, and performs as well as the predicate devices.