December 15, 2022

Nanofiber Solutions, Inc.
Ronald Bracken
President and COO
4389 Weaver Court North
Hilliard, Ohio 43026

Re: K173544
Trade/Device Name: Phoenix Wound Matrix
Regulatory Class: Unclassified
Product Code: QSZ

Dear Ronald Bracken:

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 March 2, 2018. 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

March 2, 2018

Nanofiber Solutions, Inc.
Ronald Bracken
President and COO
4389 Weaver Court North
Hilliard, Ohio 43026

Re: K173544
Trade/Device Name: Phoenix Wound Matrix
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 15, 2017
Received: November 16, 2017

Dear Ronald Bracken:

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.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173544

Device Name
Phoenix Wound Matrix

Indications for Use *(Describe)*
The Phoenix Wound Matrix is intended for use in the management of wounds. Wound types include: Partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic 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, 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.

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"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

SUBMITTER'S INFORMATION

Owner: Nanofiber Solutions, Inc

Address: 4389 Weaver Court North
Hilliard, OH 43026

Official Correspondent: Ronald L. Bracken
770-597-7656
ronny.bracken@nanofibersolutions.com

Date Summary Prepared: March 1, 2018

DEVICE INFORMATION

Name of Device: Phoenix Wound Matrix

Common/Usual Name: Wound Dressing

Classification Name: Unclassified, FRO (Dressing, wound, drug)

Predicate Device(s): K132397 GORE BIO-A Wound Matrix (FRO)
K090160 SUPRATHEL Wound & Burn Dressing (FRO)

Device Description: The Phoenix Wound Matrix is a sterile, single use device intended for the management of wounds. The Phoenix Wound Matrix is a conformable, non-woven, fibrous, three-dimensional matrix. The Phoenix Wound Matrix is made from two types of polymer fibers: Poly(lactide-co-caprolactone) and Polyglycolic acid, which are bioabsorbed after degrading via hydrolysis.

Indication for Use: The Phoenix Wound Matrix is intended for use in the management of wounds. Wound types include: Partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic 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, skin tears) and draining wounds.

Technological Characteristics: The nonwoven fibrous three-dimensional matrix comprised of Poly(lactide-co-caprolactone) and Polyglycolic acid fibers is designed to conform to the wound bed.

510(k) Summary

Comparison to Predicate Devices: The Phoenix Wound Matrix is substantially equivalent to the GORE® BIO-A® Wound Matrix (K132397) and SUPRATHEL® Wound & Burn Dressing (K090160). The Phoenix Wound Matrix raises no different questions of safety or effectiveness as compared to the predicate devices. The Phoenix Wound Matrix has the same intended use and indications for use, technological characteristics, and principles of operation as the predicate devices. There are no new novel features as compared to the Gore Bio-A and Suprathel predicate device. The minor differences between the Phoenix Wound Matrix and its predicate devices raise no different issues of safety or effectiveness.

Performance Data: The Nanofiber Solutions wound matrix has been tested for safety and performance. ISO 10993, *Biological Evaluation of Medical Devices* testing has demonstrated that the device is safe. The following testing was conducted: cytotoxicity, dermal irritation, sensitization, acute systemic toxicity, genotoxicity, 6 week muscle implantation and 6 week sub-acute/sub-chronic toxicity. Functional testing demonstrates that the device has sufficient mechanical properties (strength and flexibility) for unaged and aged devices. An animal wound healing study in a porcine model has demonstrated that there was no delay in the wound healing response due to the subject device.