January 12, 2018

Aleo BME Inc.
% LeAnn Latham
Consultant
M Squared Associates, Inc.
575 Eighth Avenue, Suite 1212
New York, NY 10018

Re: K171148
Trade/Device Name: Aleo BME Liquid Bandage
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid Bandage
Regulatory Class: Class I
Product Code: KMF
Dated: December 13, 2017
Received: December 13, 2017

Dear Ms. Latham:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171148

Device Name

Aleo BME Liquid Bandage

Indications for Use *(Describe)*

Over the counter: Aleo BME Liquid Bandage is intended to cover and protect the skin from outside dirt and microbial penetration in minor cuts, scrapes, burns, skin irritations and abrasions.

Prescription Use: Aleo BME Liquid Bandage is intended to cover and protect the skin from outside dirt and microbial penetration for minor cuts, scrapes, burns, irritations and abrasions, as well as closed surgical incisions and excisions.

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

Aleo BME Liquid Bandage

Sponsor:	Aleo BME, Inc. 200 Innovation Blvd Ste. 210A State College, PA 16803 Phone: (814) 954 7381 Fax: (814) 826 4447
Contact Person:	LeAnn Latham M Squared Associates, Inc. E-mail: leann.latham@hotmail.com Phone: (703) 562 9800
Date Prepared:	January 9, 2018
Proprietary Name:	Aleo BME Liquid Bandage
Common Name	Bandage, Liquid
Regulatory Class	Class I, 510(k)
Regulation Name, Number	Liquid bandage, 21 CFR 880.5090
Device Product Code and Panel	KMF, General & Plastic Surgery
Predicate Devices	3M Nexcare™ Liquid Bandage, K053409 KeriCure's Natural Seal™ Liquid Bandage, K131384 NewSkin® Liquid Bandage, Pre-amendment
Device Description	ALEO liquid bandage is a tough elastic skin protectant for covering minor skin cuts, scrapes, abrasions and cracks. When applied, it rapidly forms water-proof, breathable and transparent protection that forms an effective barrier to prevent microbial penetration from the external environment while the polymeric film remains intact.

Intended Use	Over the counter: Aleo BME Liquid Bandage is intended to cover and protect the skin from outside dirt and microbial penetration in minor cuts, scrapes, burns, skin irritations and abrasions. Prescription Use: Aleo BME Liquid Bandage is intended to cover and protect the skin from outside dirt and microbial penetration for minor cuts, scrapes, burns, irritations and abrasions, as well as closed surgical incisions and excisions.
Biocompatibility Testing	Aleo BME Liquid Bandage passed biocompatibility testing requirements according to ISO 10993 for Cytotoxicity (ISO 10993-5), Irritation (ISO 10993-10), sensitization (ISO 10993-10), acute systemic toxicity (ISO 10993-11), subacute/subchronic toxicity (ISO 10993-11), implantation (ISO 10993-6) and material mediated pyrogenicity (ISO 10993-11).
Shelf Life	Aleo BME Liquid Bandage is provided non-sterile. Product formulation inhibits microbial growth for preservation of the liquid bandage while in the 15 mL glass vial and on the shelf. Shelf life studies have been performed and the results indicate that the Aleo BME Liquid Bandages is safe and effective for use for the labeled shelf life.
Performance Testing	Physical, mechanical and preservative effectiveness testing results confirm that the Aleo BME Liquid Bandage meets the product design specifications. Where applicable, performance testing of the Aleo BME Liquid Bandage was compared to the predicate devices.
Substantial Equivalence	Characterization and performance tests of Aleo BME Liquid Bandage have confirmed that it is substantially equivalent in design, function and intended use to the predicate devices and confirmed that there are no significant differences between the proposed and predicate devices that raise new questions of safety or efficacy.