August 15, 2019

MEDITIME Co., Ltd
% Mr. Young Chi
CEO
Bio-Med USA Inc
27 New England Drive
Ramsey, New Jersey 07446

Re: K190264
Trade/Device Name: VIOLA
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW
Dated: June 8, 2019
Received: June 13, 2019

Dear Mr. Chi:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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 Nina Mezu-Nwaba, PharmD., MPH., MSc,
CAPT., United States Public Health Service
Assistant Director (Acting), Plastic Surgery Implant Devices Team
Division of Infection Control and Plastic Surgery Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190264

Device Name
VIOLA

Indications for Use *(Describe)*
VIOLA barbed suture comprised of dyed polydioxanone (PDO) is indicated for use in soft tissue approximation where use of absorbable suture is appropriate

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.

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510(K) Summary as required by CFR 807.92(c)

Date of Preparation: August 15, 2019

1. Sponsor

Meditime Co., Ltd.
Medical Device Complex #605,
200, Gieopdosi-ro, Jijeong-myeon, Won Ju, Gangwon Do, Rep of Korea Tel: 82 31 777 3900
Email: mexpo@daum.net

2. Contact Person

Young Chi
Bio-Med USA Inc.
27 New England Drive,
Ramsey, NJ07446, U.S.A
Tel: 1 973 278 5222
Email: biomedusa@msn.com

2. Device

Device Name: VIOLA Barbed Suture
Device Classification: Suture, Surgical, Absorbable
Polydioxanone Product Code: NEW
Device Class: Class II
Regulation Number: 21 CFR 878.4840

3. Predicate Device

K133420	TransQuill Barbed Suture	Surgical Specialities Corp

4. Description of the Device

The Viola barbed suture is a sterile, synthetic absorbable device that is intended for use in the approximation of soft tissue. It is comprised of over 99.9% of polydioxanone, and dyed with 0.05-0.075% of D&C Violet No 2. The Viola suture has 85 Cog shaped barbs distributed along the suture with a barb size of 0.567mm. The device is designed with small bi-directional barbs along the long axis of the suture monofilament to prevent sliding back and forth of the suture in tissue. VIOLA suture does not need surgical knots after tissue approximation. It is available in diameter size USP 0 through 4-0 in various lengths, and affixed to stainless steel S.S 304 needle size from 19G to 26G. The VIOLA suture is sterilized by ethylene oxide gas and packed each set in a poly bag.

5. Indication for Use

Viola barbed suture comprised of dyed polydioxanone (PDO) is indicated for use in soft tissue approximation where use of absorbable suture is appropriate.

6. Performance Tests:

Non-clinical laboratory performance testing was performed to confirm the VIOLA barbed suture comprised of polydioxanone, conforms to the USP 40-NF35:2017 monograph for absorbable sutures for tensile strength <881>, in vitro barb holding strength, and Sutures Diameter <861>, suture-needle attachment <871>. The testing was performed in accordance with FDA's Class II special controls guidance Document: Surgical Sutures, issued on Jun 3, 2003. Additional performance test was conducted to demonstrate substantial equivalence to the predicate, including in vitro post-hydrolysis tensile testing, needle tensile, elasticity, bending strength, surface structure, and pull-out test. All of the testing results met the acceptance criteria. Endotoxin level testing was conducted and will be performed on each batch of the product.

7. Biocompatibility Tests:

Biocompatibility testing was conducted on the finished final device in accordance with *Guidance for Industry and FDA Staff _ Class II Special Controls Guidance Document: Surgical Sutures* issued on Dec 19,2003 and ISO10993 *Biological Evaluation of Medical Device Part 1: Evaluation and Testing*.

8. Conclusion:

The Viola Barbed Suture is substantially equivalent to the predicate device in respect to the intended use, technological characteristics and performance. The bench performance testing and biocompatibility testing results demonstrated the subject device is as safe and effective as predicate device with the only difference being the predicate device has the suture pre-loaded with a needle and affixed. This difference does not raise any different questions of safety or effectiveness.