March 4, 2020

MumEase
% Bill Jacqmein
CEO
Medavice, Inc.
1321 Upland Drive; Suite 6792
Houston, Texas 77043

Re: K193374
Trade/Device Name: TumEase Acupressure Bracelets
Regulatory Class: Unclassified
Product Code: MVV
Dated: December 5, 2019
Received: December 5, 2019

Dear Bill Jacqmein:

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,

Heather Dean, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine 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)*

K193374

Device Name

TumEase Acupressure Bracelets

Indications for Use *(Describe)*

The acupressure bracelets are intended to reduce symptoms of nausea. Nausea may be experienced due to Travel/Motion, Pregnancy/Morning Sickness, Chemotherapy, and Anesthesia (post-procedure).

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

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter: MumEase

Company Contact Person: Catherine Varley, CEO
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Email: Catherine.Varley@mumease.com

Submission Correspondent: Bill Jacqmein, Regulatory Affairs Consultant
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Phone: (404) 216-6190
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Date Prepared: October 2019

Proprietary Name: TumEase Acupressure Bracelets

Common Name: Pressure Band, Acupressure Device

Product Code: MVV

Device Classification: Unclassified

Predicate Devices: Acu-Strap (K041877)
Pressure Right (K142471)

Device Description:

The TumEase Acupressure bracelet is a wrist bracelet that has a small round bump on the inside face of the bracelet. This small bump is manually aligned with the P6 (Neiguan or Pericardium) acupressure point. The bracelet is affixed using a Velcro strap and the desire amount of pressure is applied. One key design feature is the ability to adjust the pressure level using the "tightness" of the Velcro strap. More pressure generally increases the desired anti-nausea affect. The functionality of the Velcro strap allows each patient the ability to find the right amount of pressure for themselves based on their condition and needs. In addition, the TumEase bracelets are designed to be cosmetically attractive. It is supplied to the patient over the counter

(non-sterile). The acupressure bracelets are intended to be worn over a thin fabric. It can be used as frequently as needed by the patient.

Indications for Use:

The acupressure bracelets are intended to reduce symptoms of nausea. Nausea may be experienced due to Travel/Motion, Pregnancy/Morning Sickness, Chemotherapy, and Anesthesia (post-procedure).

Comparison to Predicate Devices:

Specification	***TumEase***	**Pressure Point (K142471)**	**Acu-Strap (K041877)**	***Comparison Result***
Indication for Use	The acupressure bracelets are intended to reduce symptoms of nausea. Nausea can be caused by a variety of causes some examples include Travel/Motion, Pregnancy/Morning Sickness, Chemotherapy and Anesthesia (post-procedure).	Pressure Right® is a drugfree, Single-Use, Pressure- Sensitive Acupressure Wrist Strip, externally applied, which is indicated for relief of nausea symptoms associated with chemotherapy, postoperative, pregnancy (morning sickness) and travel/motion.	The Acu-Strap Travel and Motion Sickness Band is intended for the relief of nausea. Nausea may be experienced due to Travel (Motion Sickness), Pregnancy (Morning Sickness), Anesthesia or Chemotherapy.	Equivalent
Over the Counter Use	Yes	Yes	Yes	Equivalent
How Supplied	Two bracelets in a plastic case with Instructions for Use	Two Wrist Straps with Instructions for Use in pouch.	Not publicly available	Equivalent
Materials	<u>Contact Point:</u> Medical Grade Stainless Steel (316) <u>Other wrist Bracelet components:</u> Cloth and Velcro Strap	<u>Contact Point:</u> Medical Grade: Lustran ABS 348; Plastic <u>Other wrist Band components:</u> 3 M Transpore Surgical Tape (adjustable).	Not publicly available	Equivalent
Dimensions	Pressure point: Diameter: 0.48	Diameter: 0.52 inches Band: 5.5 inches long	Not publicly available	Equivalent

	inches; Bracelet is 13 inches long by 1 inch wide	and 1 inch wide		
Contact Pressure	Adjustable: Lbf: 0.74 @ Normal Lbf : 0.26 @ Loose	Adjustable: 5 to 7 lbs/sq. inch (Per their 510k)	Not publicly available	Equivalent
Where Used	Wrist (over thin fabric); P6	Wrist; P6	Wrist; P6	Equivalent

Performance Testing (Bench)

Testing was conducted to compare the TumEase product to the Acu-Strap product in terms of force applied. The Acu-Strap product was selected for testing since it is approved and nonadjustable. The fixed applied pressure from the Acu-Strap product introduced less variability into the testing.

A key design advantage of the TumEase product is its adjustability in terms of acupressure delivery. This feature allows the patient to find a setting that is right for them.

As proven by the testing, the TumEase product can provide the user with a range of pressures and the Acu-Strap fixed pressure are inside of the TumEase pressure range. In addition, the "medium/normal" wear condition for the TumEase product is very close to the fixed pressure for the Acu-Strap product.

Therefore, the performance of the TumEase product was shown to be at least equivalent and could be better due to its ability to adjust to the patients' needs in terms of force delivered.

Clinical Testing

No Clinical Testing was required for this product.

Statement of Equivalence

Based on comparison of indications for use, technological features, and performance testing, the TumEase Acupressure Bracelet has been shown to be substantially equivalent to the legally marketed predicate device. This device does not raise any new safety or effectiveness questions as compared to the predicate devices.