September 1, 2021

WellSpring Pharmaceutical Corporation
% Mikel Alberdi
President
Drug Device Consulting
13014 N. Dale Mabry Hwy., #326
Tampa, Florida 33618

Re: K211823
Trade/Device Name: Bonine Acupressure Bands
Regulatory Class: Unclassified
Product Code: MVV
Dated: June 11, 2021
Received: June 14, 2021

Dear Mikel Alberdi:

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 Amber Ballard, PhD
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211823

Device Name
Bonine Acupressure Bands

Indications for Use *(Describe)*
Bonine Acupressure Bands 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 – K211823

Submission Sponsor:	WellSpring Pharmaceutical Corporation 5911 North Honore Avenue, Suite 211 Sarasota, FL 34243
Submission Correspondent:	Mikel Alberdi Drug Device Consulting 13014 N. Dale Mabry Hwy., #326 Tampa, FL 33618 Phone: (813) 708-8303 Email: malberdi@drugdeviceconsulting.com
Date Prepared:	June 11, 2021
Trade Name:	Bonine Acupressure Bands
Common Name:	Acupressure Bands
Product Code:	MVV
Classification Regulation:	Unclassified
Classification Panel:	Neurology
Device Class:	Unclassified – Pre-Amendment
Predicate Device(s):	Primary Predicate: TumEase Acupressure Bracelets K193374 510(k) Holder: MumEase Secondary Predicate: Sea-Band K033268 510(k) Holder: Sea-Band Ltd

Device Description:

Bonine Acupressure Bands are acupressure devices made of comfortable fabric band straps with Velcro closures and a dome on the buckle. Bonine Acupressure Band's acupressure dome provides gentle pressure on the Nei-Kuan or P6 pressure point in the wrist. The amount of pressure applied is fully adjustable and allows the user to increase or decrease as needed. Bonine Acupressure Bands are provided for over-the-counter use to be worn directly as desired on the consumer's wrists.

Indications for Use:

Bonine Acupressure Bands 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:

Trade Name	**Bonine Acupressure Bands**	**TumEase Acupressure Bracelet** K193374	**Sea-Band** K033268
Product Code	MVV	MVV	MVV
Regulation Number	Unclassified	Unclassified	Unclassified
Regulation Name	Device, Acupressure	Device, Acupressure	Device, Acupressure
Indications for Use	Bonine Acupressure Bands are intended to reduce symptoms of nausea. Nausea may be experienced due to Travel/Motion, Pregnancy/Morning Sickness, Chemotherapy, and Anesthesia (post-procedure).	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).	The Sea-Band Limited "Sea-Band" is indicated for the relief of nausea. Nausea is a symptom that may experienced due to a variety of causes, for example: ▪ Travel/Motion ▪ Pregnancy (Morning ▪ Sickness) ▪ Chemotherapy ▪ Post Operative
Over-The-Counter Use	Yes	Yes	Yes
How Supplied	Two bands per box	Two bracelets in a plastic case	Supplied in pairs in a plastic case
Band Material	Nylon fabric with Velcro closure	Cloth and Velcro Strap	Not publicly available
Band Dimension	10.5 in x 1 in	13 in long by 1 in wide	Not publicly available
Pressure Point Button Material	Polypropylene	Medical Grade Stainless Steel (316)	Not publicly available
Pressure Point Button Dimension	Diameter: 0.52 in Height: 0.26 in	Diameter: 0.48 in	Not publicly available
Contact Pressure	Tight: 7.8 psi Medium: 5.7 psi Loose: 4.5 psi	Not publicly available.	Not publicly available
Where used	Wrist; Nei-Kuan or (P6) acupressure point.	Wrist (over thin fabric); Nei-Kuan or (P6) acupressure point.	Wrist; Nei-Kuan or (P6) acupressure point.
Device Application	Worn on both wrists	Worn on both wrists	Worn on both wrists

Performance Testing – Nonclinical/Bench

The performance of Bonine Acupressure Bands was comparable to the predicate device and was able to provide a similar average contact pressure in the pressure point bench testing.

Performance Testing – Clinical

Not applicable. No clinical testing was conducted.

Substantial Equivalence

Bonine Acupressure Bands have the same intended use and similar characteristics as the predicate devices. The information and data provided in this submission demonstrates that any differences in the technological characteristics or materials do not raise any new questions of safety or effectiveness.

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