June 29, 2022

FridaBaby, LLC
% Angela Lassandro
Medical Device Consultant
I-Squared Group, LLC
111 Ohlinger Road
Shoemakersville, Pennsylvania 19555

Re: K220289
Trade/Device Name: FridaMom Anti-Nausea Bands
Regulatory Class: Unclassified
Product Code: MVV
Dated: May 31, 2022
Received: June 1, 2022

Dear Angela Lassandro:

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)*
K220289

Device Name
FridaMom Anti-Nausea Bands

Indications for Use *(Describe)*
The FridaMom Anti-Nausea Bands are intended to reduce symptoms of nausea which 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.

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510(k) Summary – K220289

510(k) Summary as required by 807.92(c)	
Company Information:	FridaBaby, LLC 82 NE 26th St, Suite 101 Miami, FL 33137, USA
Contact Name:	Angela F. Lassandro Medical Device Consultant angela@isquared.group 484.886.8165
Date Prepared:	29 June 2022
Device Name:	FridaMom Anti-Nausea Bands
Common Name:	Acupressure device
Classification:	Class: Unclassified (Pre-Amendment) Product Code: MVV
Equivalent Device:	TumEase Acupressure Bracelets (K193374, primary predicate) Acu-strap Travel and Motion Sickness Band (K041877, secondary predicate)
Device Description:	The FridaMom Anti-nausea Bands are adjustable wrist bands which apply pressure to the Neiguan (P6) acupressure point to relive symptoms of nausea. The bands consist of an adjustable strap with a hemi-spherical button which applies pressure to the acupressure point.
Intended Use:	The FridaMom Anti-nausea Bands are intended to reduce symptoms of nausea which may be experienced due to Travel/Motion, Pregnancy/Morning Sickness, Chemotherapy, and Anesthesia (post-procedure).
Technological Comparison:	In comparison to the equivalent devices, the FridaMom Anti-nausea Bands: • have an identical intended use • applies similar pressure profiles to the Neiguan (P6) acupressure point to relieve the symptoms of nausea • offers variable pressure and tightness with similar materials • does not have differences in safety and efficacy associated with minor technological differences in material and dimensions Refer to the Substantial Equivalence Table below for specific differences in material and dimensional specifications. As noted above, these differences have no impact in safety and efficacy of the device.
Pre-Clinical Testing Comparison:	The force applied to the Neiguan (P6) acupressure point was found to be substantially equivalent between the examined devices. Pre-clinical testing was conducted on the 1st, 50th, and 99th percentile size female wrists with the force applied by the

	subject device. The force applied by the subject device was found to be substantially equivalent to the predicate devices for each wrist size. Biocompatibility (cytotoxicity, sensitization and irritation) of the subject device was demonstrated per ISO 10993-1, ISO 10993-5 and ISO 10993-10
Clinical Data Comparison:	Clinical data are not required for the determination of substantial equivalence.
Equivalent Safety and Efficacy Conclusions:	Based on the technological and pre-clinical testing the FridaMom Anti-nausea Bands are substantially equivalent to the predicate devices. Detailed substantial equivalence discussion is shown in the Substantial Equivalence Table below.

510(k) Summary – K220289

Substantial Equivalence Table

	FridaMom Anti-nausea Bands (Subject Device)	**TumEase Acupressure Bracelets** (Primary Predicate)	**Acu-Strap Travel and Motion Sickness Band** (Secondary Predicate)	**Substantial Equivalence Discussion**
Classification	Unclassified; Product Code MVV	Unclassified; Product Code MVV, K193374	Unclassified; Product Code MVV, K041877	
Indications	The FridaMom Anti-Nausea Bands are intended to reduce symptoms of nausea which 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 may be experienced due to Travel/Motion, Pregnancy/Morning Sickness, Chemotherapy, and Anesthesia (post-procedure).	The Acu-Strap TM 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.	Identical with only slight grammatical or formatting differences which have no impact on the safety or efficacy.
Band Dimensions	Length: 240.78mm (9.48 in) Width: 16.00 mm (0.63 in)	Length: 330.2 mm (13 in) Width: 25.4 mm (1 in)	Not publicly available	The most significant technological attribute of the devices is the ability to apply pressure to the Neiguan (P6) pressure point which has been shown to be substantially equivalent. The dimensions of the subject device were selected to accommodate wrist sizes from the 1st to 90th percentile of women. The minor differences in dimensions do not impact the overall safety and efficacy of the device.
Band Material	Silicone	Cloth and Velcro	Cloth and Plastic	The most significant technological attribute of the devices is the ability to apply pressure to the Neiguan (P6) pressure point which has been shown to be substantially equivalent. Materials in both devices are well-established

				materials which do not pose safety risks to the user. The subject device has been assessed for biocompatibility. The minor differences in material do not impact the overall safety and efficacy of the device.
Pressure Point Dimensions	Ø 10.16 mm (Ø 0.4 in)	Ø12.19 mm (Ø 0.48 in)	Not publicly available	The most significant technological attribute of the devices is the ability to apply pressure to the Neiguan (P6) pressure point which has been shown to be substantially equivalent. The minor differences in dimensions do not impact the overall safety and efficacy of the device.
Pressure Point Material	ABS	Medical Grade Stainless Steel (316)	Not publicly available	The most significant technological attribute of the devices is the ability to apply pressure to the Neiguan (P6) pressure point which has been shown to be substantially equivalent. Materials in both devices are well-established materials which do not pose safety risks to the user. The subject devices has been assessed for biocompatibility. The minor differences in material do not impact the overall safety and efficacy of the device.
Pressure Point Location	Neiguan (P6)	Neiguan (P6)	Neiguan (P6)	Identical

Device Application & Features	Variable Pressure that ranges from 0.52 lbf to 0.80 lbf (achieved through holes used to select size) Non-elastic design Used on both wrists	Adjustable: Lbf: 0.74 @ Normal Lbf: 0.26 @ Loose	Non-variable pressure (one size) Elastic design Used on both wrists	The subject and primary predicate devices have a strap that allows for variable tightness using a non-elastic design. Both allow the user to control the amount of pressure and tightness of the band. The minor differences in how the variable tightness is achieved do not impact the overall safety and efficacy of the device. The secondary predicate does not offer variable pressure and relies on elastic design to accommodate wrist sizes. The differences in how variable pressure are achieve do not raise issues of safety and efficacy. All devices are used on both wrists simultaneously, raising no issues of safety or efficacy.