June 5, 2018

TAMA Research Corporation
% Robert Packard
President
Medical Devices Academy, Inc.
345 Lincoln Hill Road
Shrewsbury, Vermont 05728

Re: K173093
Trade/Device Name: TAMA BEMS device
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: May 7, 2018
Received: May 7, 2018

Dear Robert Packard:

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 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,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173093

Device Name
TAMA BEMS Device

Indications for Use *(Describe)*
The TAMA BEMS Device uses microcurrent electrical to stimulate facial tissues for aesthetic purposes

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

TAMA Research Corporation
7600 North 16th Street, Suite 205
Phoenix, AZ, 85020 USA
Tel: +1 (602) 354-8185

Contact Person: Ali Shambayati
Date Prepared: June 4, 2018

II. DEVICE

Name of Device:	TAMA BEMS Device
Classification Name:	Neurological Therapeutic Devices
Regulation:	21 CFR §882.5890
Regulatory Class:	Class II
Product Classification Code:	NFO

III. PREDICATE DEVICE

Predicate Manufacturer:	Biosonic Technologies, LLC
Predicate Trade Name:	Beautiful Image Model 900 Facial Toning Device
Predicate 510(k):	K130065

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The TAMA BEMS Device is a microcurrent stimulator producing electrical currents up to 800 micro-amps. It is intended for aesthetic purposes. It has built-in pushbuttons to allow the user to adjust the output current from 0 to 800 micro-amps, as well as changing the modality (output frequency). The BEMS device is a battery-operated device that uses a rechargeable battery. When the device is plugged into the AC outlet for charging, it becomes disabled and no treatments can be performed. The BEMS device also has LED indicators to show output intensity, battery level, and output mode. A Flow light shows when probes contact the skin, and current is flowing through the patient. If the measured current through the probes does not match the set point selected by the user, the Flow LED turns off to indicate insufficient current flow.

V. INDICATIONS FOR USE

The TAMA BEMS Device uses microcurrent electrical to stimulate facial tissues for aesthetic purposes

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

- Indications for Use
- Materials of Construction
- Design Features
- Energy Source

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

A biocompatibility certification statement was provided indicating that the components with patient contact are fabricated from biocompatible metal that is also used for other TENS devices legally marketed in the USA. In addition, cytotoxicity testing was performed to demonstrate that there are no residuals present that negatively impact biocompatibility.

Electrical safety and electromagnetic compatibility (EMC)

The following electrical safety and EMC tests have been performed:

- IEC 60601-1 Electrical Safety Testing
- IEC 60601-1-2 EMC Testing
- IEC 60601-2-10 Medical Electrical Equipment Safety Standard for Nerve and Muscle Stimulators

Software Verification and Validation Testing

Verification and validation testing of the software was conducted in accordance with IEC 62304.

Mechanical and acoustic Testing

A risk analysis was completed and risk controls were implemented in accordance with ISO 14971. Human factors testing was conducted in accordance with IEC 60601-1-6, ISO 62366 and the FDA guidance on human factors engineering to demonstrate that the ergonomics of patient and user interfaces for the subject device are substantially equivalent to the predicate device.

Animal Study

Animal performance testing was not required to demonstrate safety and effectiveness of the device.

Clinical Studies

Clinical testing was not required to demonstrate the safety and effectiveness of the TAMA BEMS Device. Instead, substantial equivalence is based upon benchtop performance testing.

The following table provides a Substantial Equivalence Comparison of TAMA BEMS with Beautiful Image Model 900 Facial Toning Device (K130065):

	TAMA BEMS Device – Subject Device	Beautiful Image Model 900 Facial Toning Device – K130065
Indications for Use	The TAMA BEMS Device uses microcurrent electrical to stimulate facial tissues for aesthetic purposes	The Beautiful Image Model 900 Facial Toning Device uses microcurrent electrical energy to stimulate facial tissues for aesthetic purposes.
Design		
Power Source	Internal 4.3V rechargeable Lithium Polymer battery	One 6V Battery
	N/A	
Method of Line Current Isolation	N/A	N/A
Patient Leakage Current	N/A	N/A
Normal Condition (μA)	N/A	N/A
Single Fault Condition (μA)		N/A
Average DC current through electrodes when device is on but no pulses are being applied (μA)	None	None
Number of Output Modes	Four	One
Number of Output Channels	One	One
Synchronous or Alternating?	N/A	N/A
Method of Channel Isolation	N/A	N/A
Manufacturer	TAMA Research Corporation	Biosonic Technologies, LLC
Regulated Current or Regulated Voltage?	Both	Both
Software/Firmware/Microprocessor Control?	Yes	Yes
Automatic Overload Trip?	Yes	Yes
Automatic No-Load Trip?	Yes	Yes
Automatic Shut Off?	Yes	Yes
User Override Control?	Yes	Yes
Indicator Display Status		
On/Off Display Status?	Yes	Yes
Low Battery?	Yes	Yes
Voltage/Current Level?	Yes	Yes
Timer Range (minutes)	0-30 minutes	None
Compliance with Voluntary Standards?	IEC60601-1	IEC 60601-1
Compliance with 21 CFR 989?	Yes	Yes
Weight (lbs., oz.)	9.5 ounces	10 lbs
Dimensions (in.) [WxHxD]	3x5x0.7	5.5x15.3x11.3
Housing Materials and Construction	Anodized aluminum 6061	Thermoplastic
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic

Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular	Rectangular
Maximum Output Voltage (volts) (+/-5%)	±0.400 @500Ω ±1.600 @2 k Ω ±8.00 @10k Ω	0.347 @500Ω 1.242 @2 k Ω 5.780 @10k Ω
Maximum Output Current (mA) (+/-5%)	±0.800 @500 Ω ±0.800 @2 k Ω ±0.800 @10k Ω	0.647 @500 Ω 0.625 @2 k Ω 0.584 @10k Ω
Duration of primary (depolarizing) phase (msec)	26.3 – 1200	0.648 – 322
Pulse Duration (msec)	52.6 – 2400	3.24 – 1610
Frequency (Hz) [or Rate (pps)]	0.045 – 2560	0.621 – 308.6
For multiphasic waveforms only: Symmetrical phases? Phases Duration (msec), (state range, if applicable), (both phases, if asymmetrical)	 Yes 26.3 – 1200	 Yes 0.324-161
Net Charge (micro coulombs (µC) per pulse) (If zero, state method of achieving zero net charge.)	0µC @500 Ω	0µC @500 Ω
Maximum Phase Charge, (µC)	400 µC positive phase, 400 µC positive phase, (50% duty cycle), all loads	190 @500 Ω
Maximum Current Density (mA/cm^2, r.m.s.)	1.591 @500 Ω **(1)**	1.486 @500 Ω
Maximum Average Current (average absolute value), mA	0.800 @500 Ω	0.493 @500 Ω
Maximum Average Power Density, (W/cm^2), (using smallest electrode conductive surface area)	318E-6 @500Ω **(2)** 0.012 @18.75 KΩ **(3)**	366E-6 @500 Ω
Burst Mode (i.e., pulse trains) (a) Pulses per burst (b) Bursts per second (c) Burst duration (seconds) (d) Duty Cycle: Line (b) x Line (c)	 5 - 20 10 - 40 0.00195 – 0.0078 0.0195 – 0.1719 **(4)**	 N/A N/A N/A N/A
ON Time (seconds)	Constant	10-30
OFF Time (seconds)	None	1-6
Additional Features (specify, if applicable)	None	None

VIII. CONCLUSIONS

Based on a comparison of indications for use, technological characteristics and performance data; it can be concluded that the TAMA BEMS Device is substantially equivalent to the predicate device.