January 2, 2019

Tivic Health Systems Inc.
% Nina Peled
Consultant
Medical Device Regulatory Consultant
550 Davis St, Unit 27
San Francisco, California 94111

Re: K182025
Trade/Device Name: ClearUP™ Sinus Pain Relief
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: November 25, 2018
Received: December 3, 2018

Dear Nina Peled:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Pamela D. Scott -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)*
K182025

Device Name
ClearUP(TM) Sinus Pain Relief

Indications for Use *(Describe)*
The Tivic Health ClearUP(TM) Sinus Pain Relief device is intended to be used for the temporary relief of sinus pain associated with Allergic Rhinitis.

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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1. **Submitter Information**

Company: Tivic Health Systems Inc.
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Menlo Park, CA 94025

Contact Person: Nina Peled
Regulatory Consultant
550 Davis St. Unit 27
San Francisco, CA 94111
npeled@yahoo.com
650 454 0322

2. **Date Prepared:** December 26.2018

3. **Device Name:** ClearUP™ Sinus Pain Relief

4. **Product Code, Class, Regulation Number and Panel**

Product Code	**Class**	**Regulation Number**	**Panel**
GZJ, Transcutaneous electrical nerve stimulator for pain relief	Class II	21.CFR 882.5890	Neurology

5. **Predicate Devices**: -Pointer excel by Lhasa Oms, Inc., K060517
-Rejuvatone MD, TSTONEMD by Trophy Skin, Inc. K152199

6. **Device Description and Principle of Operation:**

ClearUP™ Sinus Pain Relief is a handheld microcurrent stimulation device used for the temporary relief of sinus pain associated with allergic rhinitis. The unit applies a low level electrical current to the outer skin of the facial sinus passages.

The ClearUP Sinus Pain Relief unit provides a customized treatment with the following features:

- Microcurrent waveforms to relieve sinus pain associated with allergic rhinitis
- Patent-pending algorithm to locate the optimal treatment points
- Simple-to-use system of lights and vibrations to guide the user
- Small handheld shape for easy holding and comfort

7. Indications for Use:

The Tivic Health ClearUP Sinus Pain Relief device is intended to be used for the temporary relief of sinus pain associated with Allergic Rhinitis.

Over-the Counter (OTC) use:

The labeling, instructions, and user operations (21 CFR § 801.60 and 61), are designed for layman understanding and use. Proposed labeling for the device passed a Flesch-Kincaid readability test for a level of reading below 8th grade. Clinical trial users were able to operate the device without any further training or help from the clinical staff.

8. Technological Characteristics and Predicate Device Comparison

The subject device and the predicate devices use the same fundamental technology. A comparison of the subject device technology and any differences to the predicate devices is provided in the table below.

Substantial Equivalence Comparison Table

		New Device	Predicate	Predicate	Remarks
1	510k #	K182025	K060517	K152199	

		New Device	Predicate	Predicate	Remarks
2	Regulation number	882.5890	882.5890	882.5890	
3	OTC/prescription?	OTC	Prescription	OTC	
4	Product code	GZJ	GZJ	NFO	
5	Device name and model	ClearUP Sinus Pain Relief	Pointer Excel	Rejuvatone MD, Model TSTONEMD	
6	Manufacturer	Tivic Health Systems Inc.	Lhasa OMS, Inc.	Trophy Skin, Inc.	
7	Intended use	The Tivic ClearUP Sinus Pain Relief is intended to be used for the temporary relief of sinus pain associated with Allergic Rhinitis.	The Pointer-Excel is intended for use in the symptomatic relief of chronic intractable pain, postoperative pain, and acute pain.	The device is intended for facial stimulation and is indicated for over the counter cosmetic use.	
8	Power source	3.7V rechargeable battery supply	9V battery supply	9V battery (Type: 6LR61)	
	Method of line current isolation	N/A	N/A	N/A	
	Patient leakage current (µA)	0.6uA (normal condition) 0.7uA (single fault condition: humidity)	N/A	60 µA 360 µA	The new device presents reduced risk to electrical shock due to patient leakage current as it is battery-operated and is disabled when charging

		New Device	Predicate	Predicate	Remarks
9	Average DC current through electrodes when device is on but no pulses are being applied (µA)	0 µA	0	0	Device is transformer output hence no DC component to waveform
	Applied part	Type BF	Type BF	Type BF	
10	Number of output modes	1	1	1	
11	Number of output channels	1	1	1	
12	Output intensity level	3 steps, 85%, 90%, 100%	Continuously zero to full power	5 steps	
13	Regulated current or regulated voltage?	Current controlled	Current controlled	Both	No impact on risk as long as either voltage or current aspect of stimulation energy is controlled
14	Software/firmware/micro-processor control?	Yes	Yes	Yes	
15	Automatic overload trip	Not required due to circuit design	Unknown	Not required due to circuit design	

		New Device	Predicate	Predicate	Remarks
16	Automatic no load contact trip	Yes	Yes	No	The new device presents reduced impact on risk of delayed treatment. User is prompted when no contact is detected with treatment site (open load)
17	Automatic shut off	Yes	No	Yes	
18	User override control?	Yes Power on/off on the device	Yes, Normally Open stimulation activation	Yes	
19	Indicator display -On/off status -Low battery? -Voltage/ current level?	 No Yes Yes No	 No Yes Yes Yes	 No Yes No Yes	No risk impact on new device as constant current output set point is fixed
20	Timer range (minutes)	7-second treatment period	Unknown	20 minutes	
21	Weight (grams)	< 90 grams	90 grams (main device)	248 grams	
22	Dimensions (cm.) HxWxL	76x38x17 (mm)	225x50x38 mm (main device)	177.2x35x55mm	
23	Housing material and construction	Housing - ABS, Output contacts - Stainless steel -active electrode, Chrome return electrode	Housing - ABS, Output contacts - ACD12 Chrome	Housing - ABS Output contacts – ACD12 Chrome	

Output specifications:

		New Device	Predicate	Predicate	Remarks re new device
1	510k #	K182025	K060517	K152199	
2	Device name and model	ClearUP Sinus Pain Relief	Pointer Excel	Rejuvatone MD, Model TSTONEMD	
3	Waveform	Biphasic with low duty cycle	Biphasic	Pulsed monophasic	The new device presents reduced risk of tissue irritation due to net zero transfer of charge with balanced biphasic output
4	Shape	AC-coupled square	Square	Modulated square	Waveform design for optimal transfer of current across capacitive feature of skin.
6	**LOAD** 500Ω 2kΩ 10kΩ	**Stimulation** **Peak Volt / Peak mA** +/- 3V / 6mA +/- 10V / 5mA +/- 20V / 2mA	**Stimulation** **Peak Volt / Peak mA** 20V / 40mA 46V / 23mA 85V / 8.5mA	**Sensing** **Peak Volt / Peak mA** 256mV / 0.5mA 806mV/ 0.4mA 4.02V / 0.4mA	No impact on risk
9	Pulse duration (µsec)	250 µsec	260 µsec ±20%	On phase: 60 ms Off phase: 60ms Pulse width:120 ms	No impact on risk
10	Frequency (Hz)	15Hz	1-16 Hz	8.33 Hz	No impact on risk
11	Maximum phase charge (µC) 500Ω	1.5 µC	30	24.18	The new device presents reduced risk of tissue damage

		New Device	Predicate	Predicate	Remarks re new device
12	Maximum current density 500 Ω	6 mA / 0.0625 cm^2 = 96 mA/cm^2	40 mA / 0.12 cm^2 = 330 mA/cm^2	0.498 mA/cm^2 (Minimum electrode contact area 0.81 cm^2)	The new device presents reduced risk of tissue damage
13	Maximum current	2.4-2.52 mA @ 500 Ω 1.5-1.75 mA @ 2k Ω 0.6-0.7 mA @ 10k Ω	Blue zone 0 - 2 mA Black zone 2 - 45 mA ± 20% at 500 ohms loading	512 µA @ 500 Ω 403 µA @ 2k Ω 403 µA @ 10k Ω	The new device presents reduced risk of tissue damage
14	Maximum average power density @ 500 Ω	42uA * 42uA * 500 /0.0625 cm^2 = 14uW/ cm^2	160uA * 160uA * 500 / 0.12 cm^2 = 106uW/ cm^2	0.03277 (Minimum electrode contact area 0.81 cm^2)	The new device presents reduced risk of tissue damage
15	Maximum power density @ 500 ohms	6mA * 6mA * 500 /0.0625 cm^2 = 0.29W/ cm^2	40mA * 40mA *500 / 0.12 cm^2 = 6.6W/ cm^2	2.005 mW/cm^2 @ 10k Ω (Minimum electrode contact area 0.81 cm^2)	Less than the predicate device.

9. Summary of Verification and Validation activities

Bench testing passed predefined acceptance criteria. Software verification testing was carried out to ensure all device functions perform as intended. Testing was conducted and passed criteria as specified in the following standards:

- Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)], ISO, 10993-1 Edition 4: 2009-10, FDA Recognition Number: 2-220
- Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity, ANSI AAMI ISO, 10993-5 2009/(R)2014, FDA Recognition Number: 2-245
- <87> Biological Reactivity Test, In Vitro -- Elution Test, USP, 40-NF35: 2017, FDA Recognition Number: 2-252
- Medical device software - Software life cycle processes, IEC, 62304 Edition 1.1: 2015-06, FDA Recognition Number: 13-79
- Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability, IEC, 60601-1-6 Edition 3.1: 2013-10, FDA Recognition Number: 5-89
- Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators, IEC, 60601-2-10 Edition 2.1: 2016-04, FDA Recognition Number: 17-16
- Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment, IEC, 60601-1-11 Edition 2: 2015-01, FDA Recognition Number: 19-14
- Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests, IEC, 60601-1-2 Edition 4: 2014-02, FDA Recognition Number: 19-8
- Medical Devices - Part 1: Application of usability engineering to medical devices, IEC, 62366-1, Edition 1: 2015-02, FDA Recognition Number: 5-114
- C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD), ES60601-1, FDA Recognition Number 19-4
- Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications [Including: Corrigendum 1 (2013)], IEC 62133 Edition 2.0 2012-12, FDA Recognition Number 19-13
- Standard Specification for Wrought Stainless Steels for Surgical Instruments, ASTM F899-12b, FDA Recognition Number 8-343

10. Labeling Validation

A Usability/Label Comprehension Validation Study was conducted with 71 participants in order to validate the OTC appropriateness of the device labeling. The study group found that:

- 93% agreed that the device is easy to understand.
- 94% agreed that the instructions are easy to follow.
- 97% agreed that performing treatment was easy.
- 88% agreed that performing treatment was fast

11. Clinical Validation

A double-blinded randomized controlled clinical validation study was conducted at the Stanford Sinus Center to demonstrate the ability of subjects suffering from sinus pain to self-treat with the ClearUP Sinus Pain Relief device and to obtain pain relief compared to a sham/placebo device. Included were 27 sinus pain subjects with chronic rhinosinusitis, 49 patients suffering from allergic rhinitis and 5 subjects with other sinus conditions. The mean age for sham subjects was 44 and for active subjects 45 both groups had approximately 2:1 ratio of females to males.

Results from the clinical study were:

- 74% who used the microcurrent device experienced a reduction in sinus pain

- 24% who used the microcurrent device experienced sinus pain reduction of 3 points or more on the visual analog pain scale (0 no pain to 10 severe pain)

- 82% preferred ClearUP Sinus Pain Relief device to their current sinus treatment(s)

- Only one subject experienced minor reddening of the skin which disappeared within minutes.

The statistically significant results demonstrated that the ClearUp device is a safe and effective treatment for sinus pain associated with allergic rhinitis. After a single treatment, active-treated subjects exhibited a statistically significant greater mean reduction in pain than subjects using the sham device.

12. Conclusion

The ClearUP Sinus Pain Relief device has the same fundamental scientific technology, intended use, and similar output parameters I comparison to predicate devices. . The differences between the proposed device and the predicate devices do not raise new

issues of safety and effectiveness and the proposed indication for sinus pain associated with allergic rhinitis was supported by clinical performance data as described above. In conclusion, the Tivic Health ClearUP Sinus Pain Relief device is substantially equivalent to the identified predicate devices.