January 17, 2023

HillTek LLC
% Bhoomika Joyappa
Medical Device Academy Inc,
345 Lincoln Hill Road
Shrewsbury, Vermont 05738

Re: K213655
Trade/Device Name: HiTop® (Models: HiToP®4touch, HiToP®2touch, HiToP®1touch)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ, LIH
Dated: December 19, 2022
Received: December 20, 2022

Dear Bhoomika Joyappa:

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 L. Dean -S

Heather Dean, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213655

Device Name
HiTop® (Models: HiToP®4touch, HiToP®2touch, HiToP®1touch)

Indications for Use *(Describe)*
HiToP®4touch, HiToP®2touch, and HiToP®1touch is intended to be used as

Powered muscle stimulator
- Relaxation of muscle spasms
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion

TENS
- Symptomatic relief and management of chronic, intractable pain

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
K213655

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

I. SUBMITTER

HillTek LLC
421 S Brookhurst Street; Ste#142
Anaheim, CA 92804, USA
+1.206.406.9390
Contact Person: Mohammadali Nezakati
Date Prepared: November 18, 2021

II. DEVICE

Name of Device:	HiToP® (Models: HiToP®4touch, HiToP®2touch, HiToP®1touch)
Classification Name:	Physical Medicine Devices and Neurology
Regulation:	21 CFR §890.5850
Regulatory Class:	Class II
Product Classification Code:	IPF, GZJ, LIH

III. PRIMARY PREDICATE DEVICE

- Predicate Manufacturer: Mettler Electronics Corp.
- Predicate Trade Name: Sys*Stim 240
- Predicate 510(k): K113017

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The High Tone Power therapy (HiToP®) is a non-invasive electrotherapeutic device used as an Electrical muscle stimulator/ powered muscle stimulator and Transcutaneous Electrical Nerve Stimulator (TENS). The device is designed for pain management, muscle strengthening, training, muscle relaxation, and re-education. The device stimulates the underlying muscle groups through electrical impulses transmitted via electrodes applied on the skin. The device can deliver medium frequency sinusoidal electrical waves with different programmable

parameters such as frequency, duration of contraction, duration of rest, and total session duration to underlying muscle groups. In High Tone power therapy, the amplitude and the frequency are modulated simultaneously.
The High Tone Power Therapy devices (HiToP®) provide a therapy with medium frequency sine current waves ranging from 4096 – 32768 Hz. The amplitude (A) and frequency (f) of Sine waves can be simultaneously modulated, so this method is called SimulFAM® which stands for Simultaneous Frequency Amplitude Modulation.

SimulFAM®X
A frequency scan of three octaves is realized. The frequency scan is realized with different speed (0.1 - 200 Hz).

There are three models of HiToP®, which are HiToP®4 touch, HiToP®2 touch, HiToP®1 touch. Each model's intended use, working principle, product structure, and significant parameters are the same, apart from the slight difference in product appearance and number of programs. HiToP®4 touch, HiToP®2 touch, HiToP®1 touch is used at healthcare facilities and hospitals.
The device's parameters are controlled by the driver (control knob), and the user can select the desired therapy using a graphical user interface.

V. INDICATIONS FOR USE

HiToP®4 touch, HiToP®2 touch, and HiToP®1 touch is intended to be used as
Powered muscle stimulator

- Relaxation of muscle spasms
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion

TENS

- Symptomatic relief and management of chronic, intractable pain

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PRIMARY PREDICATE DEVCE

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

Device	Subject device Model HiToP®4 touch	Subject device Model HiToP®2 touch	Subject device Model HiToP®1 touch	Primary Predicate Device Sys*Stim 240	SE comparison

Submitter	HillTek LLC	HillTek LLC	HillTek LLC	Mettler Electronics Corp	-
510K Number	K213655	K213655	K213655	K113017	-
Common or Usual Name	Transcutaneous Electrical Nerve Stimulator for pain relief	Transcutaneous Electrical Nerve Stimulator for pain relief	Transcutaneous Electrical Nerve Stimulator for pain relief	Transcutaneous Electrical Nerve Stimulator for pain relief	Same
	Powered Muscle Stimulator	Powered Muscle Stimulator	Powered Muscle Stimulator	Powered Muscle Stimulator	Same
	NA	NA	NA	Infrared lamp	-
Product Code	IPF, LIH, GZJ	IPF, LIH, GZJ	IPF, LIH, GZJ	IPF, ILY, GZJ, LIH	Similar The subject device is used for electrical stimulation. It is not a Lamp, Infrared, Therapeutic Heating device. Therefore, product code ILY is not applicable to the subject device. This eliminates the risks associated with that function
Product Classification	Class II	Class II	Class II	Class II	Same
Classification Name	Stimulator, nerve, transcutaneous, for pain relief (GZJ)	Stimulator, nerve, transcutaneous, for pain relief (GZJ)	Stimulator, nerve, transcutaneous, for pain relief (GZJ)	Stimulator, nerve, transcutaneous, for pain relief (GZJ)	Same
	Stimulator, muscle, powered (IPF)	Stimulator, muscle, powered (IPF)	Stimulator, muscle, powered (IPF)	Stimulator, muscle, powered (IPF)	Same

	Interferential Current Therapy LIH	Interferential Current Therapy LIH	Interferential Current Therapy LIH	Interferential Current Therapy LIH	Same
	NA	NA	NA	Lamp, Infrared, Therapeutic Heating ILY	**Different:** The subject device is not a Lamp, Infrared, Therapeutic Heating device. Therefore, product code ILY is not applicable to the subject device. This eliminates the risks associated with that function
Regulation Number	21 CFR 890.5850	21 CFR 890.5850	21 CFR 890.5850	21 CFR 890.5850 21 CFR 890.5500	**Similar** 21 CFR 890.5500 is used for Lamp, Infrared, Therapeutic Heating device that is not applicable to the subject device. This eliminates the risks associated with that function
Indications for Use	Powered muscle stimulator • Relaxation of muscle spasms • Increase local blood circulation • Muscle re-education • Maintaining or increasing range of motion TENS	Powered muscle stimulator • Relaxation of muscle spasms • Increase local blood circulation • Muscle re-education • Maintaining or increasing range of motion TENS	Powered muscle stimulator • Relaxation of muscle spasms • Increase local blood circulation • Muscle re-education • Maintaining or increasing range of motion	Indications for Medium Frequency (Russian), Biphasic, High Volt Pulsed Current (HVPC), Interferential (4P) and Premodulated (2P3) waveforms: Relaxation of muscle spasms • Prevention or retardation of disuse atrophy	**Similar:** The indication of use is identical in both subject device and predicate devices. The additional indications for use i.e Indications for DC (Direct Current) Mode and the laser and cluster applicators in the predicate devices is not applicable for the

	• Symptomatic relief and management of chronic, intractable pain	• Symptomatic relief and management of chronic, intractable pain	TENS • Symptomatic relief and management of chronic, intractable pain	Increase local blood circulation • Muscle re-education • Maintaining or increasing range of motion Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis Indications for Microcurrent, Interferential (4P3), Premodulated (2P), Biphasic, and TENS waveforms: • Symptomatic relief and management of chronic, intractable pain • Post-traumatic acute pain • Post-surgical acute pain Indications for DC (Direct Current) Mode • Relaxation of muscle spasm The laser and cluster applicators of the	subject device as the subject device is not an Infrared, Therapeutic Heating device and does not work in DC mode

				Sys*Stim 240 emit infrared energy for: • Temporary increase in local blood circulation • Temporary relief of minor muscle and joint aches, pains and stiffness • Relaxation of muscles • Temporary relief of muscle spasms • Temporary relief of minor pain and stiffness associated with arthritis	
Type of Use	Prescription (Rx Only)	Prescription (Rx Only)	Prescription (Rx Only)	Prescription (Rx Only)	Same
Power Source(s)	100-240V~, 50-60 Hz, 200VA / AC Line	100-240V~, 50-60 Hz, 120VA / AC Line	100-240V~, 50-60 Hz, 45VA / AC Line	AC line or optional battery pack 10.8 V AC line or optional battery pack Lithium Ion	**Different:** The subject device is limited to use with AC line as the power source. The subject device does not include an optional battery pack like the predicate device, and this does not introduce any new risks. The subject device complies with IEC 60601-1 requirements for evaluation of safety. These differences do not raise different

					question of safety and effectiveness
Method of Line Current Isolation	2 MOPP	2 MOPP	2 MOPP	Yes, value unknown	**Similar:** The subject device has been tested for electrical isolation protection against electric shock according to standard requirement IEC IEC60601-1. Does not raise any safety and effectiveness concerns
Patient leakage current – normal condition (μA)	4.7 μA	4.7 μA	8.0 μA	78 μA (Less than 100 μA)	**Similar:** The subject device demonstrated electrical safety by passing ANSI AAMI ES60601-1 and IEC 60601-2-10 tests. The difference does not raise the issue of product's safety and effectiveness.
Patient leakage current – single fault condition (μA)	34μA (AC SFC 264V 60 Hz)	34μA (AC SFC 264V 60 Hz)	16.0μA (AC SFC 264V 60 Hz)	78 μA (Less than 500 μA)	
Number of Output Channels	4	2	1	2	The number of channels of output current do not affect the treatment, and the design of subject device comply with IEC60601-2-10 for performance requirement
Number of Output Modes	2	2	2	9 (one less output)	**Similar:** Two output modes of subject device are basically like two outputs of predicate

					device (Russian and Interferential). The minor difference does not raise different question of safety and effectiveness
Synchronous or alternating?	Alternating	Alternating	N/A (1 channel only)	Synchronous	Different: The subject device will not raise any safety concerns of output current by alternating stimulation mode, and the subject device complies with IEC60601-2-10 for this performance requirement. The difference does not raise different questions of safety and effectiveness
Method of Channel Isolation	Transformer isolated	Transformer isolated	Transformer isolated	Not Available	-
Regulated Current or Regulated Voltage?	Regulated Voltage (CV)	Regulated Voltage (CV)	Regulated Voltage (CV)	Not Available	The subject device complies with IEC60601-2-10 for performance requirement. So, such a minor difference does not raise different question of safety and effectiveness.
Software/Firmware/Microprocessor Control?	yes	yes	yes	yes	Same
Automatic Over current Trip? Yes/no	yes	yes	yes	yes	Same
Automatic Overload Trip? Yes/no	yes	yes	yes	yes	Same
Automatic No-Load Trip? Yes/no	yes	yes	yes	yes	Same

Automatic Shut Off? Yes/no		yes	yes	yes	yes	Same
Patient Override Control? Yes/no		yes	yes	yes	yes	Same
Patient Override Control method		Removal of patient connector at the device.	Removal of patient connector at the device.	Removal of patient connector at the device.	Patient interrupt switch	**Different:** The subject device does not have a patient interrupt switch like the predicate device. The subject device has an automatic shutdown function and an overload protection function that can monitor the unintended change in the intensity of current that can prevent the patient from unexpected conditions. the difference would not affect the safety and effectiveness of the subject device.
Indicator Display	On/Off Status? Yes/ No	Yes	Yes	Yes	Same	
	Low Battery Yes/No	No	No	No	**Different:** The subject device does not use battery for its operation. This eliminates the risks associated with that function. Therefore, the subject device will not have any safety or effectiveness concerns	

					associated with this function	
	Voltage/Current Level?	Yes	Yes	Yes	Same	
Timer Range		1 – 90 min	1 – 90 min	1 – 90 min	0-60 min	**Similar:** The timer range in the subject device is within the range or slightly above the range of the predicate device. The design of the timer range is based on the intended use. the operating time is adjustable by the operator according to physician's direction. So, the difference in timer setting range would not impact its safety and effectiveness compared to the predicate devices
Compliance with 21 CFR 898?		Yes	Yes	Yes	yes	Same
Compliance with voluntary standards • IEC60601-1 • IEC60601-1-2 • IEC60601-2-10 • ISO14971 • IEC62304 • IEC62366		Yes	Yes	Yes	Information not available	Same
Weight (lbs., oz,)		24.2508 lbs. without accessories	24.2508 lbs. without accessories	5.5 lbs. without accessories	4.5 lb.	**Different** There are minor differences between

					the subject device and the predicate devices in device weight. But the subject device complies with IEC60601-1, and IEC60601-2-10 Standard requirement. Different design criteria will have no effect on its function and does not raise safety and performance concerns
Dimensions (in.) [W x H x D]	13.77" x 11.41" x 13.77"	13.77" x 11.41" x 13.77"	10.6" x 9.64" x 2.36"	8" x 8" x13"	**Different** There are minor differences between the subject device and the predicate devices in device weight. But the subject device complies with IEC60601-1, and IEC60601-2-10 Standard requirement. Different dimensions will have no effect on its function and does not raise safety and performance concerns
Environment of use	Healthcare facilities and Hospitals	Healthcare facilities and Hospitals	Healthcare facilities and Hospitals	Information not available	Same
Electrode shape (square, round, rectangular, oval) in cm^2	Rectangular 12, 48, 96,200	Rectangular 12, 48, 96,200	Rectangular 12, 48, 96,200.	Not Available	-
Housing Material and Construction	Aluminum	Aluminum	Aluminum	ABS Plastic	**Different** There are minor differences between

					the subject device and the predicate devices in device weight. But the subject device complies with IEC60601-1, and IEC60601-2-10 Standard requirement. Different materials will have no effect on its function and does not raise safety and performance concerns

OUTPUT SPECIFICATIONS -Comparison of Subject Device Models with Predicate Rx Device

	Subject device Model HiToP4 touch	Subject device Model HiToP2 touch	Subject device Model HiToP1 touch	Predicate Device Sys*Stim 240	SE Comparison
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic	Biphasic	Medium Frequency (Russian), Biphasic, High Volt Pulsed Current (HVPC), Interferential (4P) and Pre-modulated (2P3)	**Same:** Subject device has medium frequency sine waveform same as Russian and interferential output in predicate device.
Maximum output Current (±20%)	100mA@500 Ω load 38mA@2 k Ω 7.6mA@10 k Ω	100mA@500 Ω load 38mA@2 k Ω 7.6m@10 k Ω	100mA@500 Ω load 38mA@2 k Ω 7.6m@10 k Ω	Not Available	The output current of the subject device

					complies with standard requirement of IEC60601-2-10. Therefore, the difference would not affect safety and effectiveness of the subject device. Note: As the device operates in voltage-controlled mode, it is normal that with higher resistances the current goes down.
Maximum output voltage (±20%)	76V per channel @500 Ω 76V per channel @2k Ω 76V per channel @10k Ω	76V per channel @500 Ω 76V per channel @2k Ω 76V per channel @10k Ω	76V per channel @500 Ω 76V per channel @2k Ω 76V per channel @10k Ω	Not Available	the output voltage of the subject device complies with standard requirement of IEC60601-2-10. Therefore, the difference would not

					affect safety and effectiveness of the subject device.
Frequency	4096 – 32768 Hz	4096 – 32768 Hz	4096 – 32768 Hz	Not Available	The device complies with IEC60601-1, andIEC60601-2- 10 for safety evaluation
Pulse Width	1 s – 120 s	1 s – 120 s	1.5 s – 120 s	Not Available	
Maximum Current Density, (mA/cm²)	100mA @ 500 Ω /12cm² = 8.3	100mA @ 500 Ω /12cm² = 8.3	100mA @ 500 Ω /12cm² = 8.3	Not Available	
Maximum Power Density, (W/CM²), (using smallest electrode conductive surface area)	5W / 12cm²=0.42	5W / 12cm²=0.42	5W / 12cm²=0.42	Not Available	

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

Sterilization & Shelf-life Testing

Not Applicable- Device is non-sterile.

Biocompatibility Testing

Biocompatibility assessment of conductive rubber electrodes in the subject device was performed in conformance with iso 10993-1, "biological evaluation of medical devices - part 1: evaluation and testing within a risk management process" as recognized by FDA. The following endpoints were evaluated for conductive rubber electrodes.

- Cytotoxicity – ISO 10993-5
- Skin Irritation – ISO 10993-10
- Sensitization – ISO 10993-10

NOTE:

Nylatex® wraps have not been evaluated for biocompatibility. Precautionary statements and the measures necessary to mitigate the risks in the event of an adverse event associated with the use of the Nylatex® wraps are included within the device labeling.

Electrical safety and electromagnetic compatibility (EMC)

The following electrical safety and EMC testing reports were provided:

- Electrical Safety Testing IEC 60601-1
- EMC Testing IEC 60601-1-2

- Home Use Environment IEC 60601-1-11
- Nerve and Muscle Stimulators IEC 60601-2-10

Software Verification and Validation Testing

Software verification and validation testing was provided in accordance with IEC 62304 and FDA guidance documents.

Benchtop Performance Testing

The following benchtop performance testing was provided:

- Output waveforms
- Basic unit characteristics
- Output specifications
- Uniform current distribution

Animal Study

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

Human Clinical Performance Testing

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

VII. CONCLUSIONS

Based on the comparison to the predicate device and on the outcome of non-clinical performance tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate devices and any differences between the devices do not pose any new questions of safety and effectiveness. Thus, the HiToP® models are substantially equivalent to the predicate device.