June 2, 2026

Mohammadali Nezakati
65 Enterprise Suite 400
Aliso Viejo, CA 92656

Re: K252816
Trade/Device Name: High Tone Power therapy (HiToP®) (Model: HiToP® PNP)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ
Dated: September 3, 2025
Received: September 4, 2025

Dear Mohammadali Nezakati:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

AMBER T. BALLARD -S

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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252816

Device Name
High Tone Power therapy (HiToP®) (Model: HiToP® PNP)

Indications for Use *(Describe)*
HiToP® PNP is intended to be used as:
Powered Muscle Stimulator (EMS):
-Relaxation of muscle spasms
-Increase local blood circulation
-Muscle re-education
-Maintaining or increasing range of motion

Transcutaneous Electrical Nerve Stimulator (TENS):
adjunctive use in adults to provide temporary relief of pain associated with mild to moderate diabetic peripheral neuropathy of the lower extremities.

HiToP® PNP should be applied to normal, healthy, dry, and clean skin.

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

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

I. SUBMITTER

Mohammadali Nezakati
65 Enterprise Suite 400
Aliso Viejo, CA 92656
+1.949.620.1408
Date Prepared: May 8, 2026

II. DEVICE

Name of Device:	High Tone Power therapy (HiToP®) (Model: HiToP® PNP)
Classification Name:	Powered muscle stimulator
Regulation:	21 CFR 890.5850
Regulatory Class:	Class II
Product Classification Code:	IPF, GZJ

III. PRIMARY PREDICATE DEVICE

- Predicate Manufacturer: gbo Medizintechnik AG
- Predicate Trade Name: HiToP® (Model: HiToP® 1touch)
- Predicate 510(k): K213655

IV. DEVICE DESCRIPTION

The High Tone Power therapy (HiToP® PNP) 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® PNP) 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.

HiToP® PNP is used at healthcare facilities, and hospitals. The HiToP® PNP parameters are controlled by the driver (control knob), and a graphic display that shows therapy parameters.

SimulFAM®X

A frequency scan of three octaves is realized. The frequency scan is realized with a fixed speed of 20 Hz.

V. INDICATIONS FOR USE

HiToP® PNP is intended to be used as:

Powered muscle stimulator (PMS)

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

Transcutaneous Electrical Nerve Stimulator (TENS)

- Adjunctive use in adults to provide temporary relief of pain associated with mild to moderate diabetic peripheral neuropathy of the lower extremities.

HiToP® PNP should be applied to normal, healthy, dry, and clean skin.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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

Device	Subject Device HiToP® PNP	Predicate device HiToP®1 touch	SE comparison
Submitter	M Nezakati	HillTek LLC	-
510K Number	K252816	K213655	-
Common or Usual Name	Transcutaneous Electrical Nerve Stimulator for pain relief	Transcutaneous Electrical Nerve Stimulator for pain relief	Same
	Powered Muscle Stimulator	Powered Muscle Stimulator	Same
Product Code	IPF, GZJ,	IPF, LIH, GZJ	Similar. The subject device does not include a mode for interferential current therapy, therefore, product code LIH is not applicable to the subject device.
Product Classification	Class II	Class II	Same
Classification Name	Stimulator, muscle, powered (IPF)	Stimulator, muscle, powered (IPF)	Same
	Stimulator, nerve, transcutaneous, for pain relief (GZJ)	Stimulator, nerve, transcutaneous, for pain relief (GZJ)	Same
	N/A	Interferential Current Therapy (LIH)	The subject device does not include a mode for interferential current therapy
Regulation Number	21 CFR 890.5850	21 CFR 890.5850	Same for applicable regulation
Indications for Use	HiToP® PNP is intended to be used as: Powered muscle stimulator (PMS)	Powered muscle stimulator • Relaxation of muscle spasms • Increase local blood circulation • Muscle re-education	Similar: The TENS mode of the subject device is indicated for temporary relief of pain associated with mild to moderate diabetic

	• Relaxation of muscle spasms • Increase local blood circulation • Muscle re-education • Maintaining or increasing range of motion **Transcutaneous Electrical Nerve Stimulator (TENS)** • Adjunctive use in adults to provide temporary relief of pain associated with mild to moderate diabetic peripheral neuropathy of the lower extremities. **HiToP® PNP** should be applied to normal, healthy, dry, and clean skin.	• Maintaining or increasing range of motion TENS • Symptomatic relief and management of chronic, intractable pain	peripheral neuropathy of the lower extremities, while the TENS mode of the predicate device is indicated for chronic, intractable pain. However, these differences do not alter the intended use of the device, nor do they raise different questions of safety and effectiveness relative to the predicate device.
Type of Use	Prescription (Rx Only)	Prescription (Rx Only)	Same
Power Source(s)	100-240V~, 50-60 Hz, 50VA / AC Line	100-240V~, 50-60 Hz, 45VA / AC Line	Same
Method of Line Current Isolation	2 MOPP	2 MOPP	Same
Patient leakage current – normal condition (µA)	16.0µA	8.0 µA	**Different.** However these differences do not raise different questions of safety or effectiveness. Additionally, the subject device has been tested for patient leakage current under Normal and Single fault conditions according to standard requirement IEC IEC60601-1.
Patient leakage current – single fault condition (µA)	25µA AC	16.0µA (AC SFC 264V 60 Hz)	

Number of Output Channels		1	1	Same
Number of Output Modes		1	2	**Different**: The predicate device has two output modes, SimulFAM®X and SimulFAM®i. The subject device has a fixed output mode, SimulFAM®X. These differences do not raise different questions of safety or effectiveness.
Synchronous or alternating?		Alternating	N/A (1 channel only)	**Different.** These differences do not raise different questions of safety or effectiveness. Additionally, both the subject device and the predicate device produce alternating output.
Method of Channel Isolation		Transformer isolated	Transformer isolated	Same
Regulated Current or Regulated Voltage?		Regulated Voltage (CV)	Regulated Voltage (CV)	Same
Software/Firmware/Microprocessor Control?		yes	yes	Same
Automatic Over current Trip? Yes/no		yes	yes	Same
Automatic Overload Trip? Yes/no		yes	yes	Same
Automatic No-Load Trip? Yes/no		yes	yes	Same
Automatic Shut Off? Yes/no		yes	yes	Same
Patient Override Control? Yes/no		yes	yes	Same
Patient Override Control method		Removal of patient connector at the device.	Removal of patient connector at the device.	Same
Indicator Display	On/off status? Yes/No	yes	yes	Same
	Voltage/Current Level? Yes/No	yes	yes	Same
Timer Range		30 – 60 min	1 – 90 min	**Different.** However these differences do not raise different questions of safety or effectiveness. Additionally, the

			treatment time is adjusted by the user or dependent on selected programs.
Compliance with 21 CFR 898?	Yes	Yes	Same
Compliance with voluntary standards • IEC60601-1 • IEC60601-1-2 • IEC60601-2-10 • ISO14971 • IEC62304 • IEC62366	Yes	Yes	Same
Weight (lbs., oz,)	3.08 lbs. without accessories	5.5 lbs. without accessories	**Different.** However these differences do not raise different questions of safety or effectiveness. There are minor differences between the subject device and the predicate devices in device weight and dimensions.
Dimensions (in.) [W x H x D]	9.05" x 5.11" x 9.05"	10.6" x 9.64" x 2.36"	**Different.** However these differences do not raise different questions of safety or effectiveness. There are minor differences between the subject device and the predicate devices in device weight and dimensions.
Environment of use	Healthcare facilities and Hospitals	Healthcare facilities and Hospitals	**Same**
Electrode shape (square, round, rectangular, oval) in cm^2	Rectangular 96 cm^2	Rectangular 12, 48, 96, 200 cm^2	**Similar**: The subject device using only one of the four sizes of the predicate device
Housing Material and Construction	ABS Plastic	Aluminum	**Different**. However this difference does not raise different questions of safety or effectiveness.

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

	Subject device HiToP® PNP	Predicate device HiToP® 1touch	SE Comparison
510K Number	K252816	K213655	-
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic	Same
Maximum output Current (±20%)	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	Same
Maximum output voltage (±20%)	50V per channel @500 Ω 50V per channel @2k Ω 50V per channel @10k Ω	76V per channel @500 Ω 76V per channel @2k Ω 76V per channel @10k Ω	Different. However these differences do not raise different questions of safety or effectiveness.
Carrier Frequency	4096 – 32768 Hz	4096 – 32768 Hz	Same
Modulation Frequency	20 Hz fixed	0.1 to 200 Hz adjustable	Different. However these differences do not raise different questions of safety or effectiveness. The subject device has a single fixed program. The subject device Modulation Frequency is within the range of the predicate device Modulation Frequency.
Phase Duration	15.26 to 122.07 μs	15.26 to 122.07 μs	Same
Pulse Width	Not applicable	1.5 s – 120 s	Different. However these differences do not raise different questions of safety or effectiveness. Pulse width is not applicable to HiToP devices output.
Maximum Current Density, (mA/cm²)	100mA @ 500 Ω /96cm² = 1.04	100mA @ 500 Ω /12cm² = 8.3	Different: The subject device Max Current is lower than the predicate device. Due to the different sizes of the smallest electrode surface. The differences would not affect the safety and effectiveness of the subject device.
Maximum Power Density, (W/CM²), (using smallest	5W / 96cm²=0.052	5W / 12cm²=0.42	Different: The subject device Max Power is lower than the predicate device, due to the different sizes of the

electrode conductive surface area)			smallest electrode surface. The differences would not affect the safety and effectiveness of the subject device.
Maximum Power Intensity	5W	5W	Same
Maximum Phase Charge @500 Ω	8.32 µC	10.99 µC	**Different:** The subject device Maximum Phase Charge is lower than the predicate device, due to the different sizes of the smallest electrode surface. The differences would not affect the safety and effectiveness of the subject device.

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:

Elastic straps 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 elastic straps 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.

Clinical Testing

Human clinical performance testing was provided to support the safety and effectiveness of the subject device as an adjunctive use in adults to provide temporary relief of pain associated with mild to moderate diabetic peripheral neuropathy of the lower extremities. The primary supporting study is:

Awad, Z.M., Badr, N.M., Ismail, L.A., & El-Moatasem, A.M. (2026). High-tone power therapy versus transcutaneous electrical nerve stimulation on polyneuropathic pain in diabetic patients. *Physiotherapy Research International*. 31:e70163. doi:10.1002/pri.70163

This randomized controlled trial enrolled 60 male patients with type 2 diabetes and mild to moderate diabetic peripheral neuropathy pain. Patients were randomized to receive either HiToP® PNP or Enraf-Nonius TENS applied to the lower extremities for 30 minutes per session, three times per week, over approximately three months. The primary outcomes were the Douleur Neuropathique 4 (French for "Neuropathic Pain 4", DN4) questionnaire and pain pressure threshold (PPT). The study demonstrated statistically significant improvements in both primary outcomes, with larger improvements observed in the HiToP® PNP group compared to the TENS group. DN4 scores decreased 26% in the HiToP group versus 14% in the TENS group, with a statistically significant difference between-group difference (mean difference: -0.87, 95% CI: -1.17 to -0.56, p=0.001). Pain pressure threshold increased 20.9% in the HiToP group versus 10.9% in the TENS group (between-group mean difference: 0.3, 95% CI: 0.1 to 0.5, p=0.001). Only minor adverse effects were reported, including mild skin irritation and transient fatigue, with no serious adverse events observed.

VII. CONCLUSIONS

Based on the comparison to the predicate device (K213655, HiToP® 1touch) and on the outcomes of non-clinical and clinical performance tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device and any differences between the devices do not pose any new questions of safety and effectiveness. Thus, the HiToP® PNP is substantially equivalent to the predicate device.