May 27, 2026

Motion Informatics ltd.
% Orly Maor
Company Regulatory Consultant
RA Regulation
25a Sirkin St.
Kfar Saba, 4442157
Israel

Re: K260142
Trade/Device Name: StimelMD (SSMD) system
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: April 26, 2026
Received: April 27, 2026

Dear Orly Maor:

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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260142

Please provide the device trade name(s).

StimelMD (SSMD) system

Please provide your Indications for Use below.

1. Relaxation of muscle spasms
2. Prevention of the retardation of disuse atrophy
3. Increasing local blood circulation
4. Stroke Rehabilitation by muscle re- education
5. Maintaining or increasing range of motion.
6. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
StimelMD (SSMD) system
K260142

Date Prepared: January 6, 2026

I. SUBMITTER

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II. DEVICE

Name of Device: StimelMD (SSMD) system
Common or Usual Name: SSMD
Classification Name: Powered muscle stimulator
Regulatory Class: Class II, per 21 CFR 890.5850
Product Code: IPF
Classification Panel: Physical Medicine

III. PREDICATE DEVICE

The predicate device is the Spatial StimelMD (SSMD) (former STIMEL-03), cleared under K130424 (product code IPF Regulation No. 21 CFR 890.5850).

IV. DEVICE DESCRIPTION

The SSMD is a Powered Muscle Stimulator with biofeedback. The device is portable, battery powered muscular electrical stimulator with biofeedback used as a training system for rehabilitation of paralyzed muscles, mainly after stroke.

The same controls are implemented in the current modified device. The treatment parameters are managed by the healthcare provider/user via a companion (therapist) application.

The App is used by the healthcare provider to configure treatment protocols, monitor session performance, review patient progress, and generate analytical reports. It is a web application that is operated using a desktop or mobile platforms and interfaces with the Stimel Unit via Bluetooth and with the cloud backend via Wi-Fi communication.

Device Parts and accessories:
1. Stimel Unit – the main device box that produces the treatment.

2. Disposable Electrodes – surface bi-directional electrodes to capture the EMG signal from the patient and transfer the electrical stimulation to the patient.
3. Patient cable – connecting the Stimel unit to the Disposable Electrodes.
4. Charger – AC/DC Battery Charger (110/220 VAC; 12V DC)
5. Meta Quest 3 AR headset – of-the-shelf part, provides AR animations and serves as patient's interface during treatment.

V. INDICATIONS FOR USE

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Stroke Rehabilitation by muscle re-education
5. Maintaining or increasing range of motion.
6. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Motion Informatics Ltd. Spatian StimelMD (SSMD) Subject device	**Motion Informatics Ltd. Spatian StimelMD (SSMD) (STIMEL-03)**	**SE determination**
K number	K260142	K130424	
Regulation	890.5850	890.5850	Same
Product Code	IPF	IPF	Same
Indications for Use	1. Relaxation of muscle spasms 2. Prevention of the retardation of disuse atrophy 3. Increasing local blood circulation 4. Stroke Rehabilitation by muscle re- education 5. Maintaining or increasing range of motion. 6. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis Powered muscle stimulators should only be used under medical supervision for	1. Relaxation of muscle spasms 2. Prevention of the retardation of disuse atrophy 3. Increasing local blood circulation 4. Stroke Rehabilitation by muscle re-education 5. Maintaining or increasing range of motion. 6. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis Powered muscle stimulators should only be	Same
	Motion Informatics Ltd. Spatian StimelMD (SSMD) Subject device	**Motion Informatics Ltd. Spatian StimelMD (SSMD) (STIMEL-03)**	**SE determination**

	adjunctive therapy for the treatment of medical diseases and conditions	used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions	
Power Source during Treatment	Battery Type 12V (Rechargeable Ni-MH battery 12V, 2200mAh)	Battery Type 12V (Rechargeable Li-ion battery, INP18650-4S1P, 2600mAh)	Similar No influence on safety
	Method of Line Current Isolation- Not physically possible to connect the charge adapter and the electrodes at the same time	Method of Line Current Isolation- Not physically possible to connect the charge adapter and the electrodes at the same time	Same
	Patient Leakage Current: Not physically cable is completely isolated	Patient Leakage Current: Not physically cable is completely isolated	Same
	Normal condition 0 µA	Normal condition 0 µA	Same
	Single fault Condition 0 µA	Single fault Condition 0 µA	Same
Power Source during Charging	Input Voltage100-240VAC	Input Voltage100-240VAC	Same
	Frequency 50-60 Hz	Frequency 50-60 Hz	Same
	Input Current330 mA (in battery charge mode from charger)	Input Current330 mA (in battery charge mode from charger)	Same
	Classification -Internally powered, continuous operation, type BF applied parts	Classification -Internally powered, continuous operation, type BF applied parts	Same
Number of Output Modes	1 Mode Pulse Waveform Intensity Maximum Voltage Positive/Negative Pulse Duration Total Pulse Duration Min/Max Load Pulse Repetition Rate	1 Mode Pulse Waveform Intensity Maximum Voltage Positive/Negative Pulse Duration Total Pulse Duration Min/Max Load Pulse Repetition Rate	Same
Number of Output Channels	One output channel that can be operated either Synchronous or	One output channel that can be operated either Synchronous or	Same
	Motion Informatics Ltd. Spatian StimelMD (SSMD) Subject device	**Motion Informatics Ltd. Spatian StimelMD (SSMD) (STIMEL-03)**	**SE determination**
	Alternating.	Alternating.	

	Method of Channel Isolation Channel Isolated by Transformer.	Method of Channel Isolation Channel Isolated by Transformer.	Same
Indicator Display	- On/Off Status - Low Battery - Voltage/Current Level	- On/Off Status - Low Battery - Voltage/Current Level	Same
Electrode type	2"X2" RE-PLY TENS 654	2"X2" RE-PLY TENS 654	Same
Additional features	-	Headset (off the shelf)	Different however not a safety issue as the treatment parameters were not changed
	-	Software App The App is a replica of the physical buttons that were on the previous cleared device	Different however not a safety issue as the treatment parameters were not changed

PERFORMANCE DATA

The following performance data were conducted. The SSMD System met the predetermined acceptance criteria ensuring substantial equivalence to the predicate. No new safety or effectiveness issues were raised during testing:

Software Validation

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions". Cybersecurity was also evaluated.
The tests passed.
In addition, cybersecurity information was provided.

Electrical Safety and EMC

Electrical Safety per IEC 60601-1 and Electromagnetic compatibility (EMC) per IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11 and IEC 60601-2-10 were conducted on the SSMD System. The tests passed.

VII. CONCLUSIONS

Motion Informatics Ltd. has demonstrated that the modified SSMD System is substantially equivalent in fundamental design, technology, function, device materials, packaging, operating

principal, and intended use/ indication for use to the predicate device, the cleared STIMEL-03 System.

The minor differences do not raise any new questions of safety or effectiveness. Performance data demonstrates that the modified SSMD is as safe and effective as the cleared STIMEL-03.

Thus, the SSMD System is substantially equivalent to its predicate device.