May 6, 2021

Remed Co., Ltd
% Kyungyoon Kang
CEO
K-Biotech
201 South 4th Street, Suite 727
San Jose, California 95112

Re: K202031
Trade/Device Name: Talent-Pro Electromagnetic Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: January 25, 2021
Received: February 8, 2021

Dear Kyungyoon Kang:

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 to pic. 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,

Patrick Antkowiak, PhD
Assistant Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202031

Device Name
Talent-Pro™ Electromagnetic Stimulator

Indications for Use *(Describe)*
The Talent-Pro™ Electromagnetic Stimulator is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

The Talent-Pro™ Electromagnetic Stimulator is indicated for use in stimulating neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes.

Indications for Use for Muscle Stimulators:
- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

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

Pursuant to Section 510(k) of Chapter V of the Federal Food, Drug, and Cosmetic Act and in accordance with subpart E of Part 807, Title 21 of the Code of Federal Regulations, REMED Co., Ltd. submits the following information as premarket notification for the proposed device, Talent-Pro Electromagnetic Stimulator.

I. SUBMITTER

- Company: REMED Co., Ltd.
- Address: #301-#303 Migun Techno World II, 187, Techno 2-Ro, Yuseong-gu, Daejeon, Republic of Korea, Postal code: 34025
- Tel: 82-42-934-5560
- Fax: 82-42-934-5562
- 510(k) Number: TBD

510(k) Lead: Seong Hyeon Kim, K-Bio Solutions Manager (sarah.kim@kbiotechsolutions.com, Tel: 82-2-597-2700)

Date Prepared: June 22nd, 2020

II. PROPOSED DEVICE

- Type of Submission: Traditional Premarket Notification
- Trade Name of Device: Talent-Pro Electromagnetic Stimulator
- Classification Name of Device: Stimulator, Muscle, Powered
- Review Panel: Physical Medicine
- Regulation Number: 21 CFR 890.5850
- Regulatory Class: Class II
- Product Code: IPF

III. PREDICATE DEVICE

HPM-6000 (K160992, Manufacturer: BTL Industries, Inc.)
The predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Talent-Pro Electromagnetic Stimulator is indicated for use in stimulating neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes, prevention or retardation of disuse atrophy. Talent-Pro Electromagnetic Stimulator consists of the Main body, Transducer for magnetic stimulation

The proposed, Talent-Pro Electromagnetic Stimulator is substantially equivalent to the predicate device, HPM-6000 (K160992, Manufacturer: BTL Industries, Inc.).

The intended use and indications for use of the proposed device are identical to the predicate device. The fundamental scientific, and technological characteristics of the proposed Talent-Pro Electromagnetic Stimulator and principles of Talent-Pro Electromagnetic Stimulator operation are similar to the predicate, except differences primarily shown in the product dimensions, which are assessed not to raise different questions in terms of safety and effectiveness compared to the predicate device.

V. INDICATIONS FOR USE

The Talent-Pro™ Electromagnetic Stimulator is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

The Talent-Pro™ Electromagnetic Stimulator is indicated for use in stimulating neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes.

Indications for Use for Muscle Stimulators:
- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed Talent-Pro Electromagnetic Stimulator and predicate device, HPM-6000 (K160992) share the same intended use and indications for use.

The fundamental technological characteristics and critical functional features of the Talent-Pro Electromagnetic Stimulator are similar to the predicate device, HPM-6000 (K160992). The minor differences in the external appearance and dimensions of the products do not raise different questions in safety and effectiveness compared to the predicate device. The favorable results of the design verification and electrical safety testing of the Talent-Pro Electromagnetic Stimulator have demonstrated that the proposed device has met the predetermined design requirements and the FDA's recognized standards, including the electrical safety and performance standards and EMC standards as the same as the predicate device.

The design and function of the Talent-Pro Electromagnetic Stimulator do not involve a new or different technological principle that would be considered to raise different questions in safety and effectiveness compared to the predicate device. The principle of operation, critical function and clinical use and application are the same as the predicate device, HPM-6000 (K160992).

Detailed comparisons of intended use/indications for use, technological characteristics and critical functional features between the proposed and predicate devices are provided in Table 1 below.

Table 1: Substantial Equivalence Assessment

Comparison Item	Proposed Device	Predicate Device	Assessment of Substantial Equivalence
Trade/Device Name	Talent-Pro Electromagnetic Stimulator	HPM-6000	N/A
Product Code and Regulation	21 CFR 890.5850 IPF-Stimulator, Muscle, Powered	21 CFR 890.5850 IPF-Stimulator, Muscle, Powered	Same
510k Number	N/A	K160992	N/A
Manufacturer	REMED Co., Ltd.	BTL Industries, Inc.	N/A
Application	Muscle Stimulation	Muscle Stimulation	Same
Intended Use/Indications for Use	The Talent-Pro™ Electromagnetic Stimulator is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. The Talent-Pro™ Electromagnetic Stimulator is indicated for use in stimulating neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes. Indications for Use for Muscle Stimulators: - Relaxation of muscle spasms - Prevention or retardation of disuse atrophy - Increasing local	The HPM-6000 device is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. The HPM-6000 device is indicated for use in stimulating neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes. Indications for Use for Muscle Stimulators: -Relaxation of Muscle Spasms -Prevention or Retardation of Disuse Atrophy -Increasing Local Blood Circulation -Muscle Re-education -Immediate Post-	Same

	blood circulation - Muscle re-education - Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis - Maintaining or increasing range of motion	Surgical Stimulation of Calf Muscles to Prevent Venous Thrombosis -Maintaining or Increasing Range of Motion	
Electrical Protection	Class II, BF	Class II, BF	Same
Interface	Touch screen	Touch-Screen	Same
Type of Energy	Magnetic Field	Magnetic Field	Same
Type of Applicator	Single Magnetic Coil	Single Magnetic Coil	Same
Number of Magnetic Coils in the Applicator	1	1	Same
Number of Applicators	2	2	Same
Color Touch Screen	8 inch 20.32 cm 800 x 480 pixel	8.4 inch 21.3 cm 800 x 400 pixel	Similar A minute difference in the touch screen size, and enhanced resolution quality with a higher level of pixel do not raise new questions of safety and effectiveness.
Type of Operation	Continuous	Continuous	Same
Pulse Repetition Range	1-150 Hz	1-150 Hz	Same
Magnetic Field Intensity	Applicator A: 1:00-2.5T Applicator B: 1:00-2.5T	299-1 applicator:0.5-1.8T 299-2 applicator:0.7-2.5T	Similar
Pulse Duration (±20%)	280μs	280μs	Same
Pulse Amplitude	0-100%	0-100%	Same
Therapy Time	Up to 60 min	Up to 60 min	Same
Operating Temperature	10-30^{o}C	10-30^{o}C	Same

Operating Humidity	30-85%	30-75%	Similar
Shape of Stimulation Pulse	Sine, Biphasic	Sine, Biphasic	Same
Energy Source	120V~, 60Hz, 1500A	100-240 V AC, 50-60 Hz, Max 14A	Talent-Pro's energy source is set up to be applicable to the US customer's use.
External Exchangeable Fuse	Yes	Yes	Same
System Dimensions (Width x Height x D/Length)	541.6 x500.7 x1072.9 mm (21.3 x 19.7 x 1072.9 in)	500 x 580 x 230 mm (20 x 23 x 9 in)	Similar, a minor difference in the overall external dimensions is not expected to raise different questions of the device profile in safety and effectiveness compared to the predicate.
System Weight	60 kg (132.3 lb)	33 kg (73lb)	Similar
Position	Vertical-On Castors	Vertical-On Castors	Same

VII. SAFETY & PERFORMANCE DATA

The following safety and performance data were provided in support of this substantial equivalence determination.

- **Biocompatibility Testing**

In order to meet the FDA's consensus standards for biocompatibility requirements identified in the FDA Guidance titled, "Use of ISO 10993-1, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing within a Risk Management Process (Issued June 16, 2016)", GLP biocompatibility testing of the proposed, Talent-Pro Electromagnetic Stimulation System has been completed with the favorable results of the biocompatibility testing.

Our biocompatibility risk assessments of the Talent-Pro Electromagnetic Stimulation System have concluded that it is warranted no additional biocompatibility testing of the proposed device is necessary.

Biocompatibility Testing Evaluations of Talent-Pro Electromagnetic Stimulation System Per ISO 10993 and FDA Guidance (June 16, 2016):

- Cytotoxicity
- Repeated Patch Dermal Sensitization Test (GLP - Buehler Method Modified for Medical Devices)
- ISO Primary Skin Irritation Test

- **Design Verification and Validation Testing**

Design Verification and Validation (DV&V) testing was performed to verify that the proposed Talent-Pro Electromagnetic Stimulator meets the pre-defined safety and performance requirements. Testing was also conducted to verify the effectiveness of the implemented risk control measures to mitigate the risks identified within the risk management process (per ISO 14971:2012, Medical Devices - Application of Risk Management to Medical Devices). The following design verification, or performance testing of Talent-Pro Electromagnetic Stimulator have been completed with the favorable test results, meeting the applicable ISO standards and FDA's recognized consensus standards related to evaluation of performance of Talent-Pro Electromagnetic Stimulator.

The favorable results of the design verification and validation tests have demonstrated that the design output of the proposed Talent-Pro Electromagnetic Stimulator matches its design input and is appropriate to be used for the intended use, which support its substantially equivalent profile to the predicate device.

The following design verification, validation, electrical safety and performance testing of the Talent-Pro Electromagnetic Stimulator have been comprehensively completed with the favorable test results:

Design Verification Performed (Safety and Performance Testing)

- CH1 Magnetic Field Output Magnetic Field Strength Test
- CH2 Magnetic Field Output Magnetic Field Strength Test
- CH1 Magnetic Field Intensity Control Performance Test
- CH2 Magnetic Field Intensity Control Performance Test
- CH1 Magnetic Field Stimulation Pulse Width Test
- CH2 Magnetic Field Stimulation Pulse Width Test
- CH1 Magnetic Field Stimulation Pulse Frequency Test
- CH2 Magnetic Field Stimulation Pulse Frequency Test
- Stability Test of Magnetic Field Output
- Magnetic Field Safety Device Test
- Simultaneous Operation Prevention Test
- Medical Device Inspection Test

IEC Electrical Safety and Performance Testing

- IEC 60601-1
- IEC 60601-1-6
- IEC 62366
- IEC 60601-2-10
- IEC 60601-1-2

➢ **Shipping Validation**

- Shipping Validation Test

The results of the shipping validation test demonstrate that the proposed, Talent-Pro Electromagnetic Stimulator has met all the pre-determined shipping validation test requirements.

VIII. CONCLUSIONS

In conclusion, the proposed Talent-Pro Electromagnetic Stimulator is assessed to be substantially equivalent to the predicate device, HPM-6000 (K160992). The proposed Talent-Pro Electromagnetic Stimulator shares the same intended use, indications for use and operation principle as the predicate device, HPM-6000 (K160992). The technological characteristics of the Talent-Pro Electromagnetic Stimulator are similar to the predicate and the minor differences are assessed not to raise different questions in terms of safety and effectiveness.

The comprehensive evaluations of the Talent-Pro Electromagnetic Stimulator along with the aforementioned design verification and validation testing assessments provide assurance that the Talent-Pro Electromagnetic Stimulator has met the predetermined design requirements per the FDA's recognized consensus standards which have been applied to the predicate device in the same manner.

The comprehensive assessments all point to the conclusion that the Talent-Pro Electromagnetic Stimulator is substantially equivalent to the predicate, HPM-6000 (K160992).