February 25, 2022

Shenzhen Dongdixin Technology Co., Ltd.
Siping Yuan
R.A. Specialist
Floor 1-2, No.3 Building, Fanshen Xusheng Industrial Estate
Xilixiaobaimang Nanshan District
Shenzhen, Guangdong 518108
China

Re: K213043
Trade/Device Name: Levator Elite (Model LE9011)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF, KPI, HCC, GZJ
Dated: January 20, 2022
Received: January 27, 2022

Dear Siping Yuan:

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,

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
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)*
K213043

Device Name
Levator Elite (Model LE9011)

Indications for Use *(Describe)*

NMES
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

EMG Triggered Stimulation (ETS) (nonimplanted electrical continence device only)
Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detrusor muscles through reflexive mechanisms and strengthening of pelvic floor muscles
Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles (abdominal or gluteal)

TENS
Symptomatic relief and management of chronic (long-term), intractable pain
Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain

EMG
Biofeedback, relaxation muscle training and muscle re-education

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.

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510(k) SUMMARY

as required by section 21 CFR 807.92

Levator Elite (Model LE9011)

Date of Submission: 02/25/2022

Submitter's Name: Shenzhen Dongdixin Technology Co., Ltd.

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Contact: Siping Yuan

1. Proposed Device:

Proprietary Name: Levator Elite(Model LE9011)
Classification Name: Stimulator, Muscle, Powered
Regulation #: 21 CFR 890.5850
Panel: Physical Medicine
Regulatory Class: Class II
Product Code: IPF, KPI, GZJ, HCC

2. Predicate Device:

Predicate Device	510(k)	Trade Name	Manufacturer
Predicate Device1	K201290	Medline DeNovo 4Pro Electrical Stimulation Device	Medline Industries Inc
Predicate Device2	K201014	MyOnyx System	Thought Technology Ltd.

3. Device Description:

Levator Elite(Model LE9011) is a single channel, hand-held, non-sterile, battery-powered, multi-patient device intended to be used by adult patients under the supervision of a trained clinical healthcare provider. The device contains EMG biofeedback, TENS (Transcutaneous Electrical Nerve Stimulation), ETS (EMG triggered stimulation) and NMES (Neuromuscular Electrical Stimulator). Each of them has pre-set and custom programs. The parameters of the device are controlled by the buttons, the levels of intensity are adjustable to the needs of the patient and treatments prescribed by their healthcare providers.

The device is designed to provide safe and effective electrical stimulation by sending small electrical currents to underlying nerves and muscle groups via electrode pads applied on the skin or through a vaginal probe/rectal probe (for incontinence treatment protocols only). It can be used with or without linkage to a PC. Connecting the device with the PC via USB cable, the data can be transmitted between PC and device (It needs purchase the PC software Nu-Tek System and USB connection cable).

For EMG biofeedback, EMG is for detecting the signal of muscle, which display muscle strength via EMG biofeedback bar graph or waveform format viewed on the LCD screen of the unit. Surface EMG is used for recording from superficial muscles in clinical or kinesiological protocols, where intramuscular electrodes are used for investigating deep muscles or localized muscle activity.

For NMES, NMES is the elicitation of muscle contraction using electric impulses. The impulses are generated by a device and delivered through the electrodes in direct proximity to the muscles to be stimulated or via the probe. The impulses mimic the action potential coming from the central nervous system, causing the muscles to contract. NMES is both a form of electrotherapy and of muscle training. Neuromuscular Stimulation has been used to stimulate muscle and nerve fibers for muscle strengthening, maintenance of

muscle mass and strength during prolonged periods of immobilization, selective muscle retraining.

For ETS (i.e. EMG triggered stimulation), ETS involves initiating a voluntary contraction for a specific movement until the muscle activity reaches a threshold level. As soon as the EMG activity reaches a target threshold then an assisting electrical stimulus begins which helps to support the contracted muscle. A microprocessor connected to the surface electrodes, vaginal probe or rectal probe monitors the EMG activity levels as well as administers the neuromuscular stimulation. The target threshold could be set to automated regime, when it goes up and down depending on the running muscle performance.

For TENS, the device provides a non-invasive, low-risk nerve stimulation in order to reduce pain (both acute and chronic). In TENS, mild electrical impulses are transmitted through the skin via surface electrodes to relieve muscle pain by modifying the body's pain perception. TENS does not cure problematic physiological conditions: it only helps to control the pain perception.

LE9011 consists of the following elements:

- Main device
- Pedestal
- Lead wire
- Electrode pad
- Vaginal probe
- Rectal probe (optional)
- PC Software(optional)
- USB Cable(optional)

4. Indications for Use:

NMES

- 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

EMG Triggered Stimulation (ETS) mode (nonimplanted electrical continence device only):

- Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscles through reflexive mechanisms and strengthening of pelvic floor muscles
- Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles (abdominal or gluteal)

TENS

- Symptomatic relief and management of chronic (long-term), intractable pain
- Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain

EMG

- Biofeedback, relaxation muscle training and muscle re-education

5. Comparison of Technological Characteristic

Comparison of proposed device and predicate device

No.	Item	Proposed device	Primary Predicate device	Secondary Predicate device	S.E. Discussion
1	510K#	**K213043**	**K201290**	**K201014**	**N/A**
2	Device Name and Model	Levator Elite(Model LE9011)	Medline DeNovo 4Pro Electrical Stimulation Device	MyOnyx System	N/A
3	Manufacturer	Shenzhen Dongdixin Technology Co., Ltd.	Medline (Sponsor) Verity (Manufacturer)	Thought Technology Ltd.	N/A
4	Product Code	IPF KPI HCC GZJ	IPF KPI HCC GZJ GZI	KPI HCC	Similar, the proposed device does not have FES function.
5	Classification Code	Class II	Class II	Class II	Same
6	Regulation Number	21 CFR 890.5850 21 CFR 876.5320 21 CFR 882.5050 21 CFR 882.5890	21 CFR 890.5850 21 CFR 876.5320 21 CFR 882.5050 21 CFR 882.5890 21 CFR 882.5810	21 CFR 876.5320 21 CFR 882.5050	Similar, the proposed device does not have FES function.
7	Indications for use	NMES ● 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	For EMG mode: - Relaxation muscle training and muscle re-education For NMES (also known as STIM) mode: - Relaxation of muscle spasms - Prevention or retardation of disuse atrophy - Increasing local blood	The MyOnyx System is indicated for acute and ongoing treatment of stress, urge, or mixed urinary incontinence, where urinary control may be improved through electrical stimulation that strengthens the	Similar, the proposed device does not have FES function.

		● Maintaining or increasing range of motion EMG Triggered Stimulation (ETS) (nonimplanted electrical continence device only): ● Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscles through reflexive mechanisms and strengthening of pelvic floor muscles ● Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles (abdominal or gluteal) TENS ● Symptomatic relief and management of chronic (long-term),intractable pain ● Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain EMG ● Biofeedback, relaxation muscle	circulation - Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis - Maintaining or increasing range of motion - Muscle Re-Education For TENS mode: - Symptomatic relief and management of chronic (long-term), intractable pain - Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain For EMG Triggered Stimulation (ETS) mode (nonimplanted electrical continence device only): -Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscles through reflexive mechanisms and strengthening of pelvic floor muscles -Incontinence treatment for assessing EMG activity of the	pelvic floor muscles or inhibits the detrusor muscle through reflexive mechanisms. The system also uses EMG-based or pressure-based biofeedback to help control and strengthen the pelvic floor muscles in the treatment of urinary incontinence.	

		training and muscle re-education	pelvic floor and accessory muscles (abdominal or gluteal) For FES - Helps to relearn voluntary motor functions of the extremities		
8	Prescription vs. OTC	Prescription Use	Prescription Use	Prescription Use	Same
9	Sterile vs. Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Same
10	Waveforms	Symmetrical Biphasic	●Symmetrical Biphasic DC zero[TENS and HAN (TENS)] ●Symmetrical Biphasic [NMES]	Symmetrical, rectangular, bipolar, biphasic	Same
11	Target Population	Adult	Adult	Adult	Same
12	Power Source	DC 6V, 4*AA batteries	4x AA NiMh 4.8V Rechargeable Battery pack	Internal Battery (not user replaceable): Rechargeable (3200mAh) Li-ion Polymer battery certified to IEC 62133 – up to 8 hours of autonomous device operation; External 15W, 5V Medical Grade (Class II Double Insulated) Power Supply /Battery Charger	Different, but the proposed device has passed the testing according to the requirement of IEC60601-1. The difference does not raise any safety issue.

13	Electrical Type	Type BF	Type BF	Type BF	Same
14	Patient Leakage Current (μA) -Normal condition	1uA	N/A Battery Operated Device (<100 μA patient leakage)	/	Different, but the proposed device has passed the testing according to the requirement of IEC60601-1. The difference does not raise any safety issue.
15	Patient Leakage Current (μA) -Single fault condition	N/A	N/A Battery Operated Device (<100 μA patient leakage)	/	Same
16	Number of Output Modes	Two ●Muscle stimulator: Electrodes ●TENS (Transcutaneous electrical nerve stimulator): Electrodes	Two ●Muscle stimulator: Electrodes ●TENS (Transcutaneous electrical nerve stimulator): Electrodes	One ●Muscle stimulator: Electrodes	Same with primary predicate device.
17	Number of Output Channels	1	4	4	Different, the number of output channels is the feature of device, doesn't affect the safety and effectiveness.
18	Synchronous or Alternating?	N/A, one channel	Synchronous and Alternating	/	Different, the proposed device has one channel.
19	Method of Channel Isolation	N/A, one channel	Each channel is the middle of an H bridge. Each channel is in a high impedance state except when it is activated for a specific output pulse	/	
20	Regulated	Constant current	Constant current on all four	Constant current	Same

	Current or Regulated Voltage?		channels		
21	Software/Firmware/ Micro processor Control?	Yes	Yes	Yes	Same
22	Automatic Overload Trip	Yes	No Device can withstand indefinite short circuit	Yes	Different, but the proposed device has passed the testing according to the requirement of IEC60601-1. The difference does not raise any safety issue.
23	Automatic No Load contact Trip	Yes	Yes	Yes	Same
24	Automatic Shut off	Yes	Yes	Yes	Same
25	User Override Control?	Yes	Yes	Yes	Same
26	Indicator Display: - On/Off - Low Battery? - Voltage/ Current Level?	Yes	Yes	Yes	Same
27	Compliance with Voluntary Standards?	Yes IEC 60601-1:2005+A1:2012 IEC60601-1-2 IEC 60601-1-6 IEC 60601-2-10	Yes IEC 60601-1:2005+A1:2012 IEC60601-1-2 IEC 60601-1-6 IEC 60601-2-10	Yes IEC/ES 60601-1 (Ed. 3.1) IEC 60601-1-6 IEC 60601-2-10	Similar

			FCC PART 15 Subpart B:2008 Class B FCC CFR Title 47 Part 15 Subpart C	IEC 60601-2-40 IEC 60601-1-2 (4th Ed.)	
28	Compliance with 21 CFR 898?	Yes. leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages	Yes. leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages	Yes.	Same
29	Weight (grams.)	158g without batteries	160 grams (0.35 lbs) without batteries and other accessories	272g	Different, the different weight and dimension doesn't affect the safety and effectiveness.
30	Dimensions (mm.)	139×68×32mm	96×160×36mm	155×83×20.95mm	
31	Housing Materials & Construction	Plastic (Injection Molded ABS)	Plastic (Injection Molded ABS)	Polycarbonate and ABS blend; Plexiglass tinted front panel, aluminum ring for structural support	Same with primary predicate device.
NMES Waveform					
1	Shape	Symmetrical Biphasic	● Symmetrical rectangular Biphasic [TENS and HAN (TENS)] ● Symmetrical rectangular Biphasic [NMES]	--	Similar
2	Max Output Voltage (V)	45V @500Ω 70V @2kΩ	45V @500Ω 70V @2kΩ	--	Same

	±10%	70V @10kΩ	70V @10kΩ (open lead detected above 0.5 [mA])		
3	Max Output Current (mA) ±10%	90mA @500Ω 35mA @2kΩ 7mA @10kΩ	90mA @500Ω 35 mA @2kΩ 7 mA @10kΩ (open lead detected above 0.5 [mA])	--	
4	Pulse Width	50-450µs	50-450µs in 10µs step to 100µs and thereafter 25µs up to 450µs	--	Same
5	Frequency (Hz)	2-100Hz	2-100Hz in 1Hz steps from 2 to 20Hz thereafter in steps of 5Hz up to 100Hz	--	Same
6	Net Charge (µC/pulse)	0 µC	0 µC	--	Same
7	Maximum Phase Charge (µC) 500Ω	40.5µC [90mA for 450µs]	40.5(µC) [90mA for 450µs]	--	Same
8	Average Current(I_{RMS}, 500Ω)	27mA	Not publicly available	--	Same
9	Maximum Average Current Density 500Ω	Electrode pad: 1.42 mA/cm²	1.42mA /sq cm for electrode of 19sq cm	--	Same
10	Maximum Average Power Density	Electrode pad: 19 mW/cm²	19[mW/cm²] @ 500Ω for Electrode of 19sq cm	--	Same
11	On Time (sec)	2-99 secs	2-99 secs	--	Same
12	Off Time (sec)	2-99 secs	2-99 secs	--	Same

13	Treatment Time(min)	1-99 minutes	2-99 minutes	--	Similar
TENS Waveforms					
1	Shape	Symmetrical Biphasic	Symmetrical rectangular Biphasic [TENS and HAN (TENS)]	--	Same
2	Max Output Voltage (V) ±10%	40V @500Ω 70V @2kΩ 70V @10kΩ	40V @500Ω 70V @2kΩ 70V @10kΩ (open lead detected above 0.5 [mA])	--	Same
3	Max Output Current (mA) ±10%	80mA @500Ω 35 mA @2kΩ 7 mA @10kΩ	80mA @500Ω 35 mA @2kΩ 7 mA @10kΩ (open lead detected above 0.5 [mA])	--	
4	Pulse Width	50-450μs	50-450μs in 5μs steps	--	Same
5	Frequency (Hz)	2-120Hz	2-120Hz in 1Hz steps from 2 to 20Hz thereafter in steps of 5Hz up to 100Hz	--	Same
6	Net Charge (μC/pulse)	0 μC	0 μC	--	Same
7	Maximum Phase Charge (μC) 500Ω	36μC [80mA for 450μs]	not publicly available	--	Same
8	Average Current(I_{RMS}, 500Ω)	26.3mA	not publicly available	--	Same
9	Maximum Average	Electrode pad: 1.38 mA/cm²	not publicly available	--	Same

	Current Density 500Ω				
10	Maximum Average Power Density	Electrode pad:18 mW/cm²	not publicly available	--	Same
11	On Time (sec)	N/A	N/A	--	Same
12	Off Time (sec)	N/A	N/A	--	Same
13	Treatment Time(min)	1-99 minutes	0-99 minutes	--	Similar
Incontinence Programs (For vaginal probe only)					
1	Shape	Symmetrical Biphasic	Symmetrical Rectangular Biphasic	--	Same
2	Max Output Voltage (V) ±10%	45V @500Ω 70V @2kΩ 70V @10kΩ	40V @500Ω 70V @2kΩ 70V @10kΩ (open lead detected above 0.5 [mA])	--	Same
3	Max Output Current (mA) ±10%	90mA @500Ω 35 mA @2kΩ 7mA @10kΩ	90mA @500Ω 35 mA @2kΩ 7 mA @10kΩ (open lead detected above 0.5 [mA])	--	
4	Pulse Width	50-450µs	50-450µs in 5µs steps	--	Same
5	Frequency (Hz)	2-120Hz	2-120Hz in 1Hz steps from 2 to 20Hz thereafter in steps of 5Hz up to 100Hz	--	Same
6	Net Charge （µC/pulse）	0 µC	0 µC	--	Same
7	Maximum Phase Charge	40.5µC [90mA for 450µs]	40.5(µC) [90mA for 450µs]	--	Same

	(μC) 500Ω				
8	Average Current(I_{RMS}, 500Ω)	29.5mA	not publicly available	--	Similar. The difference is because that our vaginal probe has a different surface area, which leads to slightly different max current/power density
9	Maximum Average Current Density 500Ω	Vaginal probe NT1041: 3.9mA/cm²	Everyway Incontinence Stimulation Electrode: 4.2mA/cm^2	--	
10	Maximum Average Power Density	Vaginal probe NT1041: 57mW/cm²	Everyway Incontinence Stimulation Electrode: 56mW/cm^2	--	
11	On Time (sec)	2-99 s	2-99 secs	--	Same
12	Off Time (sec)	2-99 s	2-99 secs	--	Same
Incontinence Programs (For rectal probe only)					
1	Stimulator Output	0-100mA	--	0-100mA	Same
2	Waveforms	Symmetrical Biphasic	--	Symmetrical, rectangular, bipolar, biphasic	
3	Charge/Pulse at 500ohms	80μC (100mA for 400μs)	--	80μC (100mA for 400μs)	
4	Frequency	5-80Hz	--	5-80Hz	
5	Pulse Width	150-400μs	--	150-400μs	
6	Ramps	0.1-9.9 seconds	--	0.1 – 9.9 seconds (0.1s increase)	Same
7	Duty Cycle	On (sec): 2-20 Off (sec): 2 -50	--	On (sec): 2-20 Off (sec): 2 -50	Same
8	Average Current(I_{RMS},	25.3mA	--	not publicly available	Same

	500Ω)				
9	Maximum Average Current Density 500Ω(Rectal probe)	6.76 mA/ cm²	--	not publicly available	Same
10	Maximum Average Power Density (Rectal probe)	86mW/cm²	--	not publicly available	Same
Biofeedback(EMG)					
1	EMG Range in μV	0-2000μV	0- 2000 in steps of 0.1μV to 20μV and thereafter steps of 1μV up to 2000μV	0-4420 μV	Same with primary predicate device.
2	EMG Bandwidth	20-500 Hz	10- 370Hz	20-500 Hz	Similar with primary predicate device, and the proposed device is equivalent with secondary predicate device.
3	EMG Signal Procession	Root Mean Square (RMS)	Root Mean Square (RMS)	Root Mean Square (RMS)	Same
4	EMG Detection	Bipolar	Bipolar	Bipolar	Same
5	Work Period (sec)	2-99 s	2-99 s	2 - 20 seconds	Same with primary predicate device.
6	Rest Period (sec)	2-99 s	2-99 s	2 - 50 seconds	Same with primary predicate device.
7	Session Duration(min)	1-99 minutes	1-99 minutes	1-120 minutes	Same with primary predicate device.
8	Feedback Modes	Line graph, Bar graph,	Line graph, Bar graph,	Line graph, Bar graph,	Similar

		Digital display, Signal linked animations Voice	Digital display, Signal linked animations	Digital display, Signal linked animations Voice	

6. Performance Data:

The following performance data are provided in support of the substantial equivalence determination:

6.1 Biocompatibility testing

The Levator Elite (Model LE9011) itself has no direct or indirect contact with the patient. The accessories (Electrode pad, Vaginal probe and Rectal probe) would be the primary patient-contacting components, as they have direct contact with the patient at the treatment site. The biocompatibility evaluation for the accessories (Electrode pad, Vaginal probe and Rectal probe) was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process". The testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

6.2 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the subject device. The system complies with the IEC 60601-1, IEC60601-1-11 and IEC 60601-2-10 standards for safety and the IEC 60601-1-2 standard for EMC.

6.3 Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern.

6.4 Output waveform Testing

For each program, oscilloscope tracing diagrams describing the electrical output waveform was provided to verify the output specifications of the device according to IEC 60601-2-10.

7. Conclusions

The intended use and basic technological characteristics of the Levator Elite (Model LE9011) is substantially equivalent with those of the Predicate device K201290 and K201014. Any technological differences do not raise new questions regarding safety and effectiveness.