July 19, 2021

InMode Ltd.
% Amit Goren
Regulatory Consultant
A. Stein - Regulatory Affairs Consulting Ltd.
18 Hata'as Str., Suite 21
Kfar Saba, 4442518
Israel

Re: K210877
Trade/Device Name: Evolve System with the T3 Applicator
Regulation Numbers: 21 CFR 878.4400
21 CFR 882.5890
21 CFR 890.5850
Regulation Name: Electrosurgical cutting and coagulation device and accessories,
Transcutaneous electrical nerve stimulator for pain relief,
Powered muscle stimulator
Regulatory Class: Class II
Product Code: PBX, GZJ, IPF
Dated: June 22, 2021
Received: June 24, 2021

Dear Amit Goren:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*

K210877

Device Name

Evolve System with the T3 Applicator

Indications for Use *(Describe)*

The Evolve System with the T3 Applicator employs RF technology or EMS-TENS technology for the treatment of selected medical conditions.

The T3 Applicator in RF mode is intended for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

The T3 Applicator in EMS mode is intended for:

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

The T3 Applicator in TENS mode is intended for:

- Symptomatic relief and management of chronic, intractable pain
- Post-surgical acute pain
- Post-trauma acute pain

The RF treatment mode and EMS/TENS mode should not be used in combination or sequentially.

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

THE EVOLVE SYSTEM WITH THE T3 APPLICATOR

510(k) Number K210877

Applicant Name:

Company Name: InMode Ltd.
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Israel
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Contact Person:

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E-mail: amit@asteinrac.com

Date Prepared: July 18, 2021

Trade Name: EVOLVE System with the T3 Applicator

Classification Name: CFR Classification section 890.5850;
(Product codes: IPF)
CFR Classification section 882.5890;
(Product codes: GZJ)
CFR Classification section 878.4400;
(Product codes: ISA)
CFR Classification section 878.4400;
(Product codes: PBX)

Classification: Class II Medical Device

Predicate Devices:

The EVOLVE System with the T3 Applicator is substantially equivalent to the following primary and secondary predicate devices.

Manufacturer	Device	510(k) No.
Primary Predicate		
Evolve System with the Tone Applicator	InMode Ltd.	K201285
Secondary Predicate		
The EVOLVE System	InMode Ltd.	K183450

Device Description:

The Evolve System with the T3 Applicator is designed to deliver non-thermal RF energy and electro-muscle and transcutaneous nerve stimulation for the treatment of different body areas for various medical applications. The Evolve System software controls and regulate the different applied energies in accordance with the user system preprograming and treatment settings. The subject device platform system is identical to the FDA-Cleared Evolve System platform (a.k.a EmBody System and the subject of K183450). The same platform system was recently FDA-Cleared for the use with the Tone Applicator (subject of K201285).

The Evolve System supports the placement of the following components:

- LCD display touch screen,
- Audio loudspeaker,
- 48V AC/DC power supply,
- Real time controller, distributor card and 2 RF generators,
- Fans

The System operates while connected to the T3 Applicator.

Following are the EVOLVE System with the T3 Applicator specifications:

Main Line Frequency (nominal):	50-60 Hz
Input Voltage (nominal):	100-240 VAC
Input Current (rms)	4A
Dimension: Console [W x H x D] Applicator [L x D]	 46cm W x 46cm D x 100cm H [18.2" W x 18.2" D x 44" H] T3 Applicator 8.9cm L x 4cm D [3.6" L x 1.6" D]
Weight Console:	33 Kg (73 lbs.)
Tone Applicator Weight:	0.16 Kg [0.4 lbs.]
EMS/TENs	
Platform modules AC/DC power supply	Converts AC input voltage (100-240Vac) to 6Vdc
Waveform	Symmetrical Biphasic
Shape	Rectangular
Intensity (output Voltage)	Up to 50 intensity level (=54 Vpeak)
Pulse Width T3 Applicator	 20 to 400 µSec
Frequency T3 Applicator	 3 to 200 Hz
RF	
Maximal Output power	75W
Frequency	1 MHz
Pulse duration	2 sec

Intended Use/Indication for Use:

The Evolve System with the T3 Applicator employs RF technology or EMS-TENS technology for the treatment of selected medical conditions.

The T3 Applicator in RF mode is intended for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

The T3 Applicator in EMS mode is intended for:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education

- Maintaining or increasing range of motion
- Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis

The T3 Applicator in TENS mode is intended for:

- Symptomatic relief and management of chronic, intractable pain
- Post-surgical acute pain
- Post-trauma acute pain

The RF treatment mode and EMS/TENS mode should not be used in combination or sequentially.

Performance Standards:

The EVOLVE System with the T3 Applicator has been tested and complies with the following FDA recognized consensus standards:

[Rec. Number 19-4] ANSI AAMI ES 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
[Rec. Number 19-8] IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
[Rec. Number 17-16] IEC 60601-2-10 Edition 2.1 2016-04 Medical Electrical Equipment - Part 2-10: Particular Requirements for The Basic Safety and Essential Performance of Nerve and Muscle Stimulators
[Rec. Number 5-89] IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
[Rec. Number 6-389] IEC 60601-2-2 Edition 6.0 2017-03 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential per

Sterilization/Disinfection/Cleaning:

The cleaning and reprocessing instructions set forth in the device user manual for all of the reprocessed device Applicator components. The handle should be thoroughly cleaned by the user by using 70% alcohol absorbed pad for at least 30 sec. The user should carefully examine the applicator components prior to their assembly and usage for complete drying and for any visible damage.

The device user manual and device labels, provide users with the proper symbolling and instructions/warnings for safe and effective device use and for a safe discard of the single use components upon their usage.

All device materials in contact with the patient are biocompatible.

Non-Clinical (Bench) Performance Data:

Bench testing was conducted to demonstrate that the EVOLVE System with the T3 Applicator performs as expected under anticipated conditions of use and to verify that the device performance meets the device design requirements.

The following tests were conducted:

- Accuracy testing of the RF output parameters
- Accuracy of electrode temperature sensors measurements
- Temperature build-up profile measurements
- Ex-vivo Tissue thermal profile
- Safety and thermal profile testing
- Testing of EMS/TENs output specifications

The bench testing results demonstrated that the device performs as expected under anticipated conditions of use.

Pre-Clinical (Animal) Performance Data:

Non-Applicable.

Clinical Performance Data:

Non-Applicable.

Substantial Equivalence:

The below table summarizes the main comparison aspects between the EVOLVE System with the T3 Applicator and the proposed predicate devices.

Characteristic	Subject Device EVOLVE System with the T3 Applicator	Primary Predicate Device EVOLVE System with the Tone Applicator K201285	Secondary Predicate Device EVOLVE System with the Tite Applicator K183450
Manufacturer	InMode Ltd.	InMode Ltd.	InMode Ltd.
Prescription/ OTC	Prescription	idem	idem
Class **Product Code**	Class II IPF GZJ ISA PBX	Class II IPF GZJ	Class II ISA PBX
Indications for Use	The EVOLVE System with T3 Applicator when used in RF mode is intended for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation. The EVOLVE System with T3 Applicator when used in EMS-TENS mode is intended for EMS mode: • Relaxation of muscle spasms	The EVOLVE System with Tone Applicator is used in EMS mode for: • Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood circulation • Muscle re-education • Maintaining or increasing range of motion • Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis	The InMode EmBody System with its designated hand pieces is intended for the treatment of the following medical conditions; • The EmBodyPLUS hand piece is intended for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement

Characteristic	Subject Device EVOLVE System with the T3 Applicator	Primary Predicate Device EVOLVE System with the Tone Applicator K201285	Secondary Predicate Device EVOLVE System with the Tite Applicator K183450
	• Prevention or retardation of disuse atrophy • Increasing local blood circulation • Muscle re-education • Maintaining or increasing range of motion • Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis TENS mode: • Symptomatic relief and management of chronic, intractable pain • Post-surgical and post-trauma acute pain The RF treatment mode and EMS/TENS mode should not be used in combination or sequentially.	In TENS mode it is used for: • Symptomatic relief and management of chronic, intractable pain • Post-surgical and post-trauma acute pain	of local blood circulation.
Target Population	Adult Population which requires treatment as specified in the indication for use	Idem	Idem
Anatomical Sites	Body parts requiring treatment as specified in the indication for use	Idem	Idem
Environment Used	Hospital or Clinic setting	Idem	Idem

Characteristic	Subject Device EVOLVE System with the T3 Applicator	Primary Predicate Device EVOLVE System with the Tone Applicator K201285	Secondary Predicate Device EVOLVE System with the Tite Applicator K183450
Applied energy	RF/EMS-TENS	EMS-TENS	RF
Design:	The EVOLVE System with T3 Applicator consists of an AC/DC power supply unit, controller, 2 RF generators and user interface including an LCD touch screen. The delivery of the RF/electrical energy is controlled by a Start/Stop button positioned on the front panel. The System supports the following components: • LCD display touch screen • Audio loudspeaker • 48V AC/DC power supply • Controller • 2 RF Generators The System operates while connected to the T3 Applicator in RF mode or in EMS/TENs mode.	The EVOLVE System with Tone Applicator consists of an AC/DC power supply unit, controller, 2 RF Generators (disabled) and user interface including an LCD touch screen. The delivery of the electrical energy is controlled by a Start/Stop button positioned on the front panel. The System supports the following components: • LCD display touch screen • Audio loudspeaker • 48V AC/DC power supply • Controller • 2 RF Generators (disabled) The System operates while connected to the Tone Applicator.	The EVOLVE System with Tite Applicator consists of an AC/DC power supply unit, controller, 2 RF generators and user interface including an LCD touch screen. The delivery of the RF energy is controlled by a Start/Stop button positioned on the front panel. The System supports the following components: • LCD display touch screen • Audio loudspeaker • 48V AC/DC power supply • Controller • 2 RF Generators The System operates while connected to the Tite Applicator.
- Components Console	The EVOLVE System consists of the following components: • Console, including a power supply unit, controller and user interface including an LCD touch screen.	The EVOVLE System consists of the following components: • Console, including a power supply unit, controller and user interface including an LCD touch screen.	The EVOVLE System consists of the following components: • Console, including a power supply unit, controller and user interface including an LCD touch screen. • 2 RF Generators

Characteristic	Subject Device EVOLVE System with the T3 Applicator	Primary Predicate Device EVOLVE System with the Tone Applicator K201285	Secondary Predicate Device EVOLVE System with the Tite Applicator K183450
	• 2 RF Generators • T3 Applicator with up to 6 units connected to the console via 6 designated cables and 6 designated connection ports.	• 2 RF Generators (disabled) • Tone applicator with up to 4 units connected to the console via 4 designated cables and 4 designated connection ports.	• Tite applicator with up to 8 units connected to the console via 8 designated cables and 8 designated connection ports.
Dimension Console [W x H x D] Applicator unit [L x D] Cable length	46cm W x 46cm D x 100cm H [18.2" W x 18.2" D x 44" H] T3 Applicator unit: 67.3mm L x 54.3mm D [2.7" L x2.2" D] 280 cm [110`` L]	46cm W x 46cm D x 100cm H [18.2" W x 18.2" D x 44" H] Tone Applicator unit: 120mm L x 100mm D [4.8" L x4.0" D] 280 cm [110`` L]	46cm W x 46cm D x 100cm H [18.2" W x 18.2" D x 44" H] Tite Applicator unit: 40.9mm L x 36.1mm D [1.6" L x1.4" D] 280 cm [110`` L]
Weight Console Weight applicator	33.0 Kg [73 lbs.] T3: 0.16 Kg [0.4 lbs.]	33.0 Kg [73 lbs.] Tone: 0.22 Kg [0.5 lbs.]	33.0 Kg [73 lbs.] Tite: 0.17 Kg [0.4 lbs.]
Applicator unit treatment area (EMS/TENS)	T3: 6.46 cm^2 (3 small electrodes 1.05x2.05x3=6.46)	Tone: 12 cm^2	
Applicator unit treatment area (RF)	T3: 33.7 cm^2		Tite: 14.8 cm^2
Performance Specifications: System			
Power Source(s)	Main Line Frequency (nominal) 50-60Hz Input Voltage (nominal) 100-240VAC Input Current (rms) 4A	Main Line Frequency (nominal) 50-60Hz Input Voltage (nominal) 100-240VAC Input Current (rms) 4A	Main Line Frequency (nominal) 50-60Hz Input Voltage (nominal) 100-240VAC Input Current (rms) 4A
RF Frequency	1 MHz	Disabled	1 MHz
Maximal RF output power	75 W	Disabled	50 W
Method of Line Current Isolation	Independent transformer isolated	Independent transformer isolated	N/A

Characteristic	Subject Device EVOLVE System with the T3 Applicator	Primary Predicate Device EVOLVE System with the Tone Applicator K201285	Secondary Predicate Device EVOLVE System with the Tite Applicator K183450
Electrical Type	Type BF	Type BF	N/A
Patient Leakage Current - Normal Condition (µA)	<100uA patient leakage	<100uA patient leakage	N/A
Patient Leakage Current - Single Fault Condition (µA)	<300uA line leakage	<300uA line leakage	N/A
Number of Output Channels	6	4	8
Synchronous or Alternating	See Output Specifications Below	See Output Specifications Below	N/A
Method of Channel Isolation	Through transformers and isolators	Through transformers and isolators	N/A
Regulated Current or Regulated Voltage (output signals only)	Regulated voltage on all channels With current limit	Regulated voltage on all channels With current limit	N/A
Software/Firmware/Microprocessor Control	Yes	Yes	N/A
Automatic Overload Trip	Yes	Yes	N/A
Automatic No-Load Trip	Yes	Yes	N/A
Automatic Shut Off	Yes, On/off switch	Yes, On/off switch	N/A
Patient Override Control	Yes	Yes	N/A
Indicator Display;			
On/Off Status	Yes	Yes	N/A
Battery	No battery	No battery	N/A
Voltage/Current level	Yes, voltage levels	Yes, voltage levels	N/A

Characteristic	Subject Device EVOLVE System with the T3 Applicator	Primary Predicate Device EVOLVE System with the Tone Applicator K201285	Secondary Predicate Device EVOLVE System with the Tite Applicator K183450
Timer Range (Minutes)	0-60 [minutes]	0-60 [minutes]	N/A
Compliance with 21 CFR 890.5850 (IPF)	Yes	Yes	N/A
Compliance with 21 CFR 882.5890? (GZJ)	Yes	Yes	N/A
Performance Specifications: Applicator	T3 Applicator	Tone Applicator	Tite Applicator
RF Output Mode			
Maximal RF output power	75 W	Deactivated	50 W
Pulse Duration	2 sec	Deactivated	2 sec
EMS Output Mode			
Output Specifications: Waveform	Symmetrical Biphasic Waveform	Symmetrical Biphasic Waveform	N/A
Pulse Shape	Rectangular	Rectangular	N/A
Maximum Output Voltage (± 10%)	30V @500Ω	56V @500Ω	N/A
	54V @2 kΩ	56V @2 kΩ	N/A
	54V @10kΩ	56V @10kΩ	N/A
Maximum Output Current (± 10%)	60 mA @ 500 Ω	92.86 mA @ 500 Ω	N/A
	27 mA @ 2 kΩ	26.7 mA @ 2 kΩ	N/A
	5.4 mA @ 10 kΩ	5.4 mA @ 10 kΩ	N/A
Intensity level (output volteage)	Up to 50 intensity level (=54 Vpeak)	Up to 50 intensity level (=54 Vpeak)	N/A
Pulse Width (µsec.) - The output active positive pulse width	20 to 400 [µs]	20 to 400 [µs]	N/A
Frequency (Hz)	3 to 200 [Hz]	3 to 200 [Hz]	N/A
Net Charge @ 500 ohms [µC/pulse]	0 [µC] @ 500Ω	0 [µC] @ 500Ω	N/A
Maximum Phase Charge [µC]	24 [µC] @ 500Ω	43.2 [µC] @ 500Ω	N/A
Maximum Current (RMS) Density [mA/cm²]	0.74 [mA/cm²] Surface = 6.46cm²	0.72 [mA/cm²] Surface = 12cm²	N/A

Characteristic	Subject Device EVOLVE System with the T3 Applicator	Primary Predicate Device EVOLVE System with the Tone Applicator K201285	Secondary Predicate Device EVOLVE System with the Tite Applicator K183450
Maximum Power Density [mW/cm²]	22.2 [mW/cm²] @500Ω	55[mW/cm²] @500Ω	N/A
Burst Mode (i.e., pulse trains) a. Pulses per burst b. Bursts per second c. Burst duration (seconds) d. Duty Cycle [Line (b) x Line (c)]	Yes: a. 3 - 200 b. 1 c. 1-60 sec d. Time on / off	Yes: a. 3 - 200 b. 1 c. 1-60 sec d. Time on / off	N/A
On Time (sec.)	1 – 60 [sec]	1 – 60 [sec]	N/A
Off Time (sec.)	1 – 60 [sec]	1 – 60 [sec]	N/A
Treatment Time (min) - the time limit that will put the system in STOP state Level	Up to 60 min.	Up to 60 min.	N/A
TENS Output Mode			
Output Specifications: Waveform	Symmetrical Biphasic Waveform	Symmetrical Biphasic Waveform	N/A
Pulse Shape	Rectangular	Rectangular	N/A
Maximum Output Voltage (± 10%)	19V @500Ω	36V @500Ω	N/A
	19V @2 kΩ	36V @2 kΩ	N/A
	19V @10kΩ	36V @10kΩ	N/A
Maximum Output Current (± 10%)	38 mA @ 500 Ω	67.8 mA @ 500 Ω	N/A
	9.5 mA @ 2 kΩ	17.7 mA @ 2 kΩ	N/A
	1.9 mA @ 10 kΩ	3.6 mA @ 10 kΩ	N/A
Intensity level (output volteage)	Up to 15 intensity level (=19 Vpeak)	Up to 50 intensity level (=54 Vpeak)	N/A
Pulse Width (µsec.) - The output active positive pulse width	20 to 400 [µs]	20 to 400 [µs]	N/A
Frequency (Hz)	3 to 200 [Hz]	3 to 200 [Hz]	N/A

Characteristic	Subject Device EVOLVE System with the T3 Applicator	Primary Predicate Device EVOLVE System with the Tone Applicator K201285	Secondary Predicate Device EVOLVE System with the Tite Applicator K183450
Net Charge @ 500 ohms [µC/pulse]	0 [µC] @ 500Ω	0 [µC] @ 500Ω	N/A
Maximum Phase Charge [µC]	15.2 [µC] @ 500Ω	28.8 [µC] @ 500Ω	N/A
Maximum Current Density [mA/cm²]	0.47 [mA/cm²] Surface = 6.46cm²	0.48 [mA/cm²] Surface = 12cm²	N/A
Maximum Power Density [mW/cm²]	8.9 [mW/cm²] @500Ω	17.3 [mW/cm²] @500Ω	N/A
Burst Mode (i.e., pulse trains) a. Pulses per burst b. Bursts per second c. Burst duration (seconds) d. Duty Cycle [Line (b) x Line (c)]	Yes: a. 3 - 200 b. 1 c. 1 – 60 sec d. Time on / off	Yes: a. 3 - 200 b. 1 c. 1 – 60 sec d. Time on / off	N/A
On Time (sec.)	1 – 60 [sec]	1 – 60 [sec]	N/A
Off Time (sec.)	1 – 60 [sec]	1 – 60 [sec]	N/A
Treatment Time (min) - the time limit that will put the system in STOP state Level	Up to 60 min.	Up to 60 min.	N/A
Biocompatibility	Materials are biocompatible	Materials are biocompatible	Materials are biocompatible
Sterility	N/A	N/A	N/A

The EVOLVE System with the T3 Applicator is a versatile machine, offering potential users with RF, EMS and TENS technology-based treatment methods for several medical indications. The subject device and predicate devices utilize the same technology, for the same indication for use, and with almost identical design specifications. The device emits RF energy or EMS-TENS electrical signals with identical power and current densities, pulse characteristics, and bear almost identical system components to its predicate devices such as; user

interface, and hardware components. All of the subject device performance specifications are equal to those of its predicate devices. The minor differences in technical specifications should not alter the device safety and effectiveness. Furthermore, the subject device had underwent the required performance testing and validation testing and demonstrates its conformance with device design requirements and with applicable standards .

The safety features and compliance with safety standards of the subject device are similar to the safety features and compliance with safety standards of the predicate devices. All user-contacting materials were tested for biocompatibility and found to comply with the ISO 10993-1 standard. Furthermore, the design and development phases of the subject device were validated throughout a set of performance tests, including software validation testing, electrical and mechanical safety testing according to IEC 60601-1 standard, electromagnetic compatibility testing according to IEC 60601-1-2 standard, safety and essential performance of nerve and muscle stimulators testing according to IEC 60601-2-10 standard, Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (IES 60601-2-2), bench, ex-vivo tissue study and thermal profile study on human volunteers performance tests. All in all, these performance tests demonstrated that the device specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Consequently, it can be concluded that the EVOLVE System with the T3 Applicator is substantially equivalent to its predicate device and can be sold in the US market.

Conclusions:
Based on the comparison to the predicate devices and on the non-clinical performance testing results demonstrating that the EVOLVE System with the T3 Applicator is as safe and effective as the predicate device, it can be concluded

that The EVOLVE System with the T3 Applicator is substantially equivalent to the primary and secondary predicate devices; The Evolve System with the Tone Applicator FDA cleared under 510(k) K201285, and the Evolve System with Tite Applicator FDA cleared under 510(k) K183450 and therefore may be legally marketed in the USA.