



September 27, 2026

Fit-Pro KFT (Ltd.) - DBA E-Fit
% Tom Cronin
Official Correspondent
Medical Device Academy, Inc.
345 Lincoln Hill Rd.
Shrewsbury, Vermont 05738

Re: K260945

Trade/Device Name: Ultima System (UL-800); Ultimate Face Package (UL-800-Face-Set); Ultimate Shape Extension Kit 1 (UL-800-Shape-Ext-Kit-1); Ultimate Shape Extension Kit 2 (UL-800-Shape-Ext-Kit-2)

Regulation Number: 21 CFR 890.5850

Regulation Name: Powered muscle stimulator

Regulatory Class: Class II

Product Code: NGX, NFO, ILY

Dated: August 28, 2026

Received: August 28, 2026

Dear Tom Cronin:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Heather L. Dean -S

Heather Dean, 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

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.

K260945

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Please provide the device trade name(s).

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Ultima System (UL-800);
Ultimate Face Package (UL-800-Face-Set);
Ultimate Shape Extension Kit 1 (UL-800-Shape-Ext-Kit-1);
Ultimate Shape Extension Kit 2 (UL-800-Shape-Ext-Kit-2)

Please provide your Indications for Use below.

?

The ULTIMA UL-800 System is intended for use in adults 22 years of age and older. The system is designated for for prescription use only in professional healthcare settings.

The ULTIMA UL-800 System provides two energy modalities, electrical stimulation and light output. Electrical stimulation has separate body NGX and facial NFO applications. Electrical stimulation and light output are operated separately and cannot be delivered simultaneously.

NGX electrical muscle stimulation function

The ULTIMA UL-800 System is intended to apply electrical current through surface electrodes to healthy muscles for muscle-conditioning purposes by temporarily affecting the stimulated muscle's contractile properties, force output, and/or fatigue resistance. The NGX function is not intended for rehabilitation or for the treatment of patients with medical conditions. NGX is available with UL-PAD-IR1 / IR2 / IR3 / IR4 for the labeled body parts.

NFO facial aesthetic electrical stimulation function

When UL-FACE is operated in the separate NFO electrical stimulation mode, the ULTIMA UL-800 System is indicated for aesthetic use including facial skin stimulation. Application is limited to the labeled forehead and cheek sites on intact skin. This function is not intended for rehabilitation, treatment of medical conditions, or conditioning of facial muscles to improve contractile properties, force output, or fatigue resistance.

ILY topical-heating light function

When UL-FACE is operated in the separate ILY light mode, the ULTIMA UL-800 System is intended to emit energy in the visible red and near-infrared spectrum to provide topical heating for the purpose of elevating tissue temperature, temporarily increasing local blood circulation, and temporarily relaxing muscles.

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

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

?

Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
☐ Infants (29 days old to < 2 years old)
☐ Children (2 years old to < 12 years old)
☐ Adolescents (12 years old to < 22 years old)
☒ Adults (22 years old and greater)

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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Fit-Pro KFT (Ltd.) - DBA E-Fit
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Correspondent Contact	Mr. Tom Cronin
Correspondent Contact Email	tom@fdaestar.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Ultima System (UL-800); Ultimate Face Package (UL-800-Face-Set); Ultimate Shape Extension Kit 1 (UL-800-Shape-Ext-Kit-1); Ultimate Shape Extension Kit 2 (UL-800-Shape-Ext-Kit-2)
Common Name	Powered muscle stimulator
Classification Name	Stimulator, Muscle, Powered, For Muscle Conditioning
Regulation Number	890.5850
Product Code(s)	NGX, NFO, ILY

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K202148	E-Fit Infinity System	NGX
K242532	BTL-785BNF-E	NFO
K212275	Dermalux Flex MD	ILY
K15133	LightStim for Pain LED Belt	ILY

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The ULTIMA UL-800 System is an externally powered, microprocessor-controlled medical electrical system. The controller includes a 15-inch TFT LCD touchscreen, rotary encoder, treatment-output electronics, safety monitoring, and manufacturer-installed software. The System separately provides electrical stimulation or infrared light output separately. UL-PAD applicators deliver electrical muscle stimulation (EMS) to labeled body locations. The UL-FACE delivers facial aesthetic transcutaneous electrical nerve stimulation (TENS) or the separate infrared topical-heating light function. The controls adjust output delivery. The ULTIMA System is mounted on a movable stand with four wheels.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The ULTIMA UL-800 System is intended for use in adults 22 years of age and older. The system is designated for for prescription use only in professional healthcare settings.

The ULTIMA UL-800 System provides two energy modalities, electrical stimulation and light output. Electrical stimulation has separate body NGX and facial NFO applications. Electrical stimulation and light output are operated separately and cannot be delivered simultaneously.

NGX electrical muscle stimulation function

The ULTIMA UL-800 System is intended to apply electrical current through surface electrodes to healthy muscles for muscle-conditioning purposes by temporarily affecting the stimulated muscle's contractile properties, force output, and/or fatigue resistance. The NGX function is not intended for rehabilitation or for the treatment of patients with medical conditions. NGX is available with UL-PAD-IR1 / IR2 / IR3 / IR4 for the labeled body parts.

NFO facial aesthetic electrical stimulation function

When UL-FACE is operated in the separate NFO electrical stimulation mode, the ULTIMA UL-800 System is indicated for aesthetic use including facial skin stimulation. Application is limited to the labeled forehead and cheek sites on intact skin. This function is not intended for rehabilitation, treatment of medical conditions, or conditioning of facial muscles to improve contractile properties, force output, or fatigue resistance.

ILY topical-heating light function

When UL-FACE is operated in the separate ILY light mode, the ULTIMA UL-800 System is intended to emit energy in the visible red and near-infrared spectrum to provide topical heating for the purpose of elevating tissue temperature, temporarily increasing local blood circulation, and temporarily relaxing muscles.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The ULTIMA UL-800 NGX body function is compared with E-Fit Infinity System (K202148) for stimulation and conditioning of healthy body muscles. The primary predicate's muscle-conditioning scope is not extended to the face.

The NFO facial function is compared directly with BTL-785BNF-E K242532 for aesthetic facial skin stimulation. ULTIMA retains a narrower anatomical scope. The shared electrical-stimulation principle and biphasic waveform support the comparison. Pulse timing, charge, applicator geometry and contact materials are explicitly evaluated as differences rather than represented as identical.

The ILY topical-heating function is compared with Dermalux Flex MD K212275 and LightStim for Pain LED Belt K15133 for tissue heating, temporary local circulation increase and temporary muscle relaxation. Their additional acne, wrinkle and pain claims are not adopted for ULTIMA.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

Device & Predicate Device(s):	K260945	K202148	K242532
General Device Characteristics	Subject Device	Primary Predicate	Secondary Predicate
NGX/NFO Electrical Stimulation			
Trade Name	Ultima System (ULTIMA UL-800)	E-Fit Infinity System (EF-100, EF-2090)	BTL-785BNF-E
Manufacturer	Fit-Pro KFT, Ltd.	Fit-Pro Ltd.	BTL Industries, Inc.
Reg. Name	Powered muscle stimulator, for muscle conditioning; Infrared therapeutic heating lamp	Powered muscle stimulator, for muscle conditioning	Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Pro. Code	NGX, NFO, ILY	NGX	NFO
Reg. Number	890.5850, 882.5890, 890.5500	890.5850	882.5890
Class	II	II	II
Intended Use	The ULTIMA UL-800 System is intended for use in adults 22 years of age and older. The system is designated for for prescription use only in professional healthcare settings. The ULTIMA UL-800 System provides two energy modalities, electrical stimulation and light output. Electrical stimulation has separate body NGX and facial NFO applications. Electrical stimulation and light output are operated separately and cannot be delivered simultaneously. NGX electrical muscle stimulation function The ULTIMA UL-800 System is intended to apply electrical current through surface electrodes to healthy muscles for muscle-conditioning purposes by temporarily affecting the stimulated muscle's contractile properties, force output, and/or fatigue resistance. The NGX function is not intended for rehabilitation or for the treatment of patients with medical conditions. NGX is available with UL-PAD-IR1 / IR2 / IR3 / IR4 for the labeled body parts. NFO facial aesthetic electrical stimulation function When UL-FACE is operated in the separate NFO electrical stimulation mode, the ULTIMA UL-800 System is indicated for aesthetic use including facial skin stimulation. Application is limited to the labeled forehead and cheek sites on intact skin. This function is not intended for rehabilitation, treatment of medical conditions, or conditioning of facial muscles to improve contractile properties, force output, or fatigue resistance. ILY topical-heating light function	E-Fit Infinity System (EF-2090 and EF-100) is a machine system with electronic muscle stimulation based on EMS technology. Regarding its use, the output power is limited and specifically designed as an addition to other sports and for toning muscles. It may only be used for healthy muscles and clients, and not to be used for rehabilitation purposes. The E-Fit Infinity system was designed to stimulate healthy muscles in order to improve or facilitate muscle performance. The E-Fit Infinity system must not be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the E Fit Infinity system training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated. The E-Fit Infinity system's electrical impulses allow the triggering of action potentials on motoneurons of motor nerves (excitations). These excitations of motoneurons are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles. The various types of muscle work that the E-Fit Infinity system can impose on the stimulated muscles are able to improve or facilitate muscle performance. The E-Fit Infinity system may therefore be considered a technique of muscle training.	The device is indicated for aesthetic use including facial and neck or body skin stimulation.

Device & Predicate Device(s):	K260945	K202148	K242532
General Device Characteristics	Subject Device	Primary Predicate	Secondary Predicate
NGX/NFO Electrical Stimulation			
Trade Name	Ultima System (ULTIMA UL-800)	E-Fit Infinity System (EF-100, EF-2090)	BTL-785BNF-E
	When UL-FACE is operated in the separate ILY light mode, the ULTIMA UL-800 System is intended to emit energy in the visible red and near-infrared spectrum to provide topical heating for the purpose of elevating tissue temperature, temporarily increasing local blood circulation, and temporarily relaxing muscles.		
Intended Users	Trained Healthcare Professionals	Trained Healthcare Professionals	Trained Healthcare Professionals
Use Environment	Professional Healthcare Facility	Professional Healthcare Facility	Prescription Use Setting
User Interface	The UL-800-ULTIMA Controller device is equipped with 15" multi touch screen and a rotary encoder. When the device is turned on the Graphical User Interface (GUI) appears on the screen. The Controller is designed to control the UL-FACE (TENS) and UL-PAD-IR (EMS) applicators. Every channel assigned to separate muscle groups can be controlled with corresponding buttons on the touchscreen display. The operating interface is used to manage the different programs and settings.	The wireless controller has rotary encoder which allows for a quick set-up, and because of the push button capability, the program can be stopped immediately for every channel. There are large START/STOP and POWER off buttons to begin the program and for complete power shutdown. Because of the pictographs on the displays and fixed electrodes in the clothing, it is very easy to set the appropriate muscle groups.	Main control unit with touchscreen controller. Stimulation is provided by a handpiece with single-use application electrodes connected via cables to the main console.
Prescription	Prescription	Prescription	Prescription
Power Source	External AC/DC Power supply; 24 V DC; 220 W	Battery 3.7 V Lithium Polymer (x2)	Mains Power, 100-240 V, 50 – 60 Hz
Treatment Time	30 min	30 min	Up to 20 min
Output Modes	Two Electrical (EMS, TENS); Infrared Light Stimulation provided independent of each other.	One EMS	One TENS
Auto-shutoff	Startup self-test, current/voltage limits, no-load/contact detection, watchdog, hardware Health Protection/relay isolation, DC blocking, safe OFF on stop/fault/reset/interruption, and no automatic restart.	Self-test, short-circuit and no-/on-load monitoring, watchdog, battery/current monitoring, emergency stop, and hardware-error monitoring.	Patient discomfort shut-off button
Electrode Materials	316L Stainless Steel	316L Stainless Steel	Conductive Silver ink
Patient Electrode Interface	Reusable stainless-steel electrode through patient-assigned UL-UC textile (96% cotton / 4% elastane), uniformly moistened only with potable water.	Electrode through 100% hygroscopic cotton moistened with tap water; no direct electrode-to-skin placement.	Electrode via electroconductive hydrogel.
Anatomical Location of Stimulation	Face (TENS): 1. M. Frontalis 2. M. Buccinator 3. M. Masseter	1. Chest 2. Arms 3. Abdominals 4. Back	Face, neck and body

Device & Predicate Device(s):	K260945	K202148	K242532
General Device Characteristics	Subject Device	Primary Predicate	Secondary Predicate
NGX/NFO Electrical Stimulation			
Trade Name	Ultima System (ULTIMA UL-800)	E-Fit Infinity System (EF-100, EF-2090)	BTL-785BNF-E
	Body (EMS): 1. Abdominis 2. Rectus Femoris 3. Vastus Medialis 4. Vastus Lateralis 5. Gluteus Maximus 6. Musculi Ischiocrurales	5. Thighs 6. Buttocks 7. Glutes 8. Hamstrings 9. Calves	
Reusable	Yes	Yes	No, Single Use electrodes
Electrode Size (cm ²)	Face: 45.21 (aggregate); Body: 114.7 (per applicator)	Not available.	1: 3.8 cm ² 2: 4.0 cm ² 7: 1.9 cm ² 8: 2.9 cm ² 9: 3.5 cm ² 11: 1.8 cm ²
Number of Channels	1 output channel, Time-separated switching to 11 outputs/channels; and electrical current can be regulated individually on every output.	1 output channel can shift in time between the 12 outputs and electrical current can be regulated individually on every output.	Not publicly available
Max Output Current (@ 500 Ω)	75 mA	75 mA	G1: 97 mA G2: 64 mA G3: 30 mA
Max Output Voltage (@ 500 Ω)	37.5 V	37.2 V	48.5 V
Max Phase Charge μ C (@ 500 Ω)	Face: 13; Body: 24	26	G1: 15 μ C G2: 10 μ C G3: 5 μ C
Max Current Density (mA/cm ²) (@ 500 Ω)	0.6538	0.9365	1: 16.8; 2: 24.3; 7: 33.7; 8: 33.5; 9: 27.7 11: 16.4 mA/cm ² Not identified as RMS.
Max Power Density (W/cm ²) (@ 500 Ω)	0.0306	0.0342	1: 0.033; 2: 0.047; 7: 0.065; 8: 0.065; 9: 0.054; 11: 0.032
Waveform	Charge-balanced biphasic rectangular pulse modulated by trapezoidal	Symmetric biphasic	Charge-balanced biphasic rectangular pulse modulated by trapezoidal
Frequency (Hz)	4 - 220	4 - 90	250
Pulse Duration	100 - 500 μ s	100 - 500 μ s	160 μ s

Device & Predicate Device(s):	K260945	K212275	K15133
General Device Characteristics	Subject Device	Secondary Predicate	Secondary Predicate
ILY Photostimulation			
Trade Name	Ultima System (UL-800-ULTIMA)	Dermalux Flex MD	LightStim for Pain
Manufacturer	Fit-Pro KFT, Ltd.	Aesthetic Technology, Ltd.	LED Intellectual Properties LLC
Reg. Name	Powered muscle stimulator, for muscle conditioning; Infrared therapeutic heating lamp	Laser Surgical Instrument for Use in General and Plastic Surgery in Dermatology	Infrared therapeutic heating lamp
Pro. Code	NGX, NFO, ILY	OLP, OHS, ILY	ILY
Reg. Number	890.5850, 882.5890, 890.5500	878.4810, 890.5500	890.5500
Class	II	II	II
Intended Use	The ULTIMA UL-800 System is intended for use in adults 22 years of age and older. The system is designated for for prescription use only in professional healthcare settings. The ULTIMA UL-800 System provides two energy modalities, electrical stimulation and light output. Electrical stimulation has separate body NGX and facial NFO applications. Electrical stimulation and light output are operated separately and cannot be delivered simultaneously. NGX electrical muscle stimulation function The ULTIMA UL-800 System is intended to apply electrical current through surface electrodes to healthy muscles for muscle-conditioning purposes by temporarily affecting the stimulated muscle's contractile properties, force output, and/or fatigue resistance. The NGX function is not intended for rehabilitation or for the treatment of patients with medical conditions. NGX is available with UL-PAD-IR1 / IR2 / IR3 / IR4 for the labeled body parts. NFO facial aesthetic electrical stimulation function When UL-FACE is operated in the separate NFO electrical stimulation mode, the ULTIMA UL-800 System is indicated for aesthetic use including facial skin stimulation. Application is limited to the labeled forehead and cheek sites on intact skin. This function is not intended for rehabilitation, treatment of medical conditions, or conditioning of facial muscles to improve contractile properties, force output, or fatigue resistance. ILY topical-heating light function When UL-FACE is operated in the	Intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. The blue spectrum light is intended to reduce mild to moderate inflammatory acne vulgaris. Intended to emit energy in the red and infrared spectrum for use in dermatology for the treatment of periorbital and full face wrinkles.	The LightStim for Pain LED Belt is an Over-The-Counter device intended to emit energy in the visible and near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain or muscle spasm, the temporary increase in local blood circulation, and the temporary relaxation of muscles.

Device & Predicate Device(s):	K260945	K212275	K15133
General Device Characteristics	Subject Device	Secondary Predicate	Secondary Predicate
ILY Photostimulation			
Trade Name	Ultima System (UL-800-ULTIMA)	Dermalux Flex MD	LightStim for Pain
	separate ILY light mode, the ULTIMA UL-800 System is intended to emit energy in the visible red and near-infrared spectrum to provide topical heating for the purpose of elevating tissue temperature, temporarily increasing local blood circulation, and temporarily relaxing muscles.		
Intended Users	Trained Healthcare Professionals	Adult Lay Users	Adult Lay Users
Use Environment	Professional Healthcare Facility	Professional and Home Use Settings	Home Use Settings
User Interface	The UL-800-ULTIMA Controller device is equipped with 15" multi touch screen and a rotary encoder. When the device is turned on the Graphical User Interface (GUI) appears on the screen. The Controller is designed to control the UL-FACE-LIFT and UL-PAD-IR applicators. Every channel – assigned to separate muscle groups - can be controlled with corresponding buttons on the touchscreen display. The operating interface is used to manage the different programs and settings.	Push button capacitive touch interface.	Push button on/off switch and timer.
Prescription	Prescription	Over the Counter	Over the Counter
Power Source	External AC/DC Power supply; 24 V DC; 220 W	Battery	Battery
Treatment Time	30 min	Up to 30 min	5 to 30 min
Output Modes	Two EMS, Red Light Stimulation provided independent of each other.	One Multiple Wavelength Photostimulation	One Multiple Wavelength Photostimulation
Photostimulation Anatomical Location	Face	Flexible array positioned for face or body treatment;	Belt with 1-4 pods for curved body areas.
Treatment Area	250 cm ²	792 cm ²	55 – 220 cm ²
Wavelengths (nm)	660, 730, 940	Red light: 633nm ±5nm Blue light: 415nm ±5nm NIR light: 830nm ±5nm	630, 660, 855, 940
Distance from Skin {1}	Min. 20 mm from skin	Not available	Direct contact
Avg. Irradiance (W/cm ²) {2}	0.0216 W/cm ²	0.0055 W/cm ² (415 nm) 0.0115 W/cm ² (633 nm) 0.0055 W/cm ² (830 nm)	0.060 W/cm ²
Radiant Exposure {3}	33.88 J/cm ²	Red: 20 J/cm ² Blue: 10 J/cm ² NIR: 10 J/cm ²	Calculated upper exposure from public values: 108 J/cm ² at 30 minutes (0.060 W/cm ² x 1,800 s).
Max Treatment Duration	Maximum 30 minutes; software timer.	Up to 30 minutes; preset timer/software controls duration.	Recommended 5-30 minutes; automatic shutoff after 30 minutes.
Ocular Safety	Mandatory OD ≥ 4 eyewear from 600-1000 nm; clean, completely dry,	Detailed eyewear/preparation values are not stated in the public	Detailed eyewear/preparation values are not stated in the public summary.

Device & Predicate Device(s):	K260945	K212275	K15133
General Device Characteristics	Subject Device	Secondary Predicate	Secondary Predicate
ILY Photostimulation			
Trade Name	Ultima System (UL-800-ULTIMA)	Dermalux Flex MD	LightStim for Pain
	product-free skin; electrodes/cotton removed; stop for excessive heat/discomfort.	summary.	

{1} Similar: delivered irradiance is characterized at the subject treatment plane and subject-specific optical, thermal, risk and usability controls address non-contact delivery. Different geometry does not raise a different question of safety or effectiveness.

{2} Same red/NIR scientific technology. LightStim provides exact 660/940 nm overlap; Dermalux supports red/NIR facial delivery; 730 nm lies within the compared red/NIR spectral region and is subject-device characterized.

{3} Similar performance: Subject Device's specified irradiance of 21.6 mW/cm² represents the cumulative output of its three simultaneously operating wavelengths, rather than the output of each wavelength individually. If the three Dermalux wavelengths are likewise operated simultaneously, their reported irradiances provide a cumulative output of approximately 22.5 mW/cm² (11.5 + 5.52 + 5.5 mW/cm²), making the total irradiance of the two devices closely comparable. LightStim, at 60 mW/cm², remains a conservative higher-output predicate comparator. The safety of the Subject Device is independently supported by its own optical and thermal performance testing.

ULTIMA's reported 48 V ceiling is comparable in magnitude to BTL's reported voltage. Its 75 mA system ceiling falls below BTL G1 at 500 Ω but exceeds G2 and G3, so electrode-group matching is essential. ULTIMA's FACEGYM phase is longer and frequency lower. The reported 24 μ C system phase charge exceeds every BTL group; the actual facial configuration must be reconciled under Note N1. Lower frequency or average power density alone does not establish equivalence.

The results of the completed evaluations and testing demonstrate that any differences do not raise different questions of safety and effectiveness, and the performance data demonstrate acceptable safety and performance compared to the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions [21 CFR 807.92\(b\)](#)

The following nonclinical testing was conducted to support the substantial equivalence determination.

The biocompatibility of the subject device is also based on the use of skin-contacting, low biocompatibility risk materials with a long history of safe use in accordance with Attachment G of the FDA's 2023 Biocompatibility Guidance.

Shelf-life

ASTM F1980-21 - accelerated age testing of the System.

Software Validation, Cybersecurity, Wireless Safety, and Interoperability

- IEC 62304 Software Lifecycle
- Cybersecurity testing

Electrical Safety & Electromagnetic Compatibility Testing

- IEC 60601-1 Electrical Safety
- IEC 60601-1-2 EMC (Immunity & Emissions Testing)
- IEC TS 60601-4-2
- IEC 62471 - Photobiological Classification
- IEC 60601-2-10 - Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 60601-2-57- Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use. Note: This is addressed through the optical report's edition-specific applicability/gap assessment; conformity to an out-of-scope edition is not claimed.

Performance Testing (non-clinical benchtop):

- Powered Muscle Stimulator (PMS) characteristics aligned to FDA's PMS Guidance
- Usability Documentation
- Optical Safety and Effectiveness

Conclusion Statement

Therefore, the ULTIMA UL-800 System has the same intended use as the predicate devices. The differences in technological characteristics do not raise new questions of safety and effectiveness, and the performance data demonstrate that the ULTIMA UL-800 System is substantially equivalent to the cleared predicate devices.