August 30, 2024

TensCare Ltd
Saskia Eldridge-Hinmers
Quality Assurance & Regulatory Affairs Executive
9 Blenheim Road
Epsom, Surrey KT19 9BE
United Kingdom

Re: K232441
Trade/Device Name: Unipro (K-UNIPRO-US)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZJ, IPF, LIH
Dated: August 28, 2024
Received: August 28, 2024

Dear Saskia Eldridge-Hinmers:

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.

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

for Pamela Scott
Assistant Director, Neuromodulation – Psychiatry Devices
DHT5B: Division of Neuromodulation and Rehabilitation 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.

Submission Number *(if known)*

K232441

Device Name

Unipro (K-UNIPRO-US)

Indications for Use *(Describe)*

TENS stands for Transcutaneous Electrical Nerve Stimulation. Unipro TENS is used to provide symptomatic pain relief for chronic, acute or post-operative pain.

EMS stands for Electrical Neuromuscular Stimulation. Unipro EMS is indicated for:
• Relaxation of muscle spasm
• Increasing local blood circulation and muscle re-education
• Prevention or retardation of disuse atrophy
• Prevention of venous thrombosis of the calf muscles immediately after surgery
• Maintaining on increasing range of motion

MIC stands for Microcurrent Stimulation. Unipro MIC is used to provide sumptomatic pain relief for chronic intractable pain, post traumatic pain or post surgical pain.

IFT stands for Interferntial Stimulation. Unipro IFT is indicated for symptomatic relief of chronic intractable pain.

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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5. 510(k) SUMMARY – K232441

5.1. Submitters Identification

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Date Prepared : 20.March. 2024

Address of the manufacturing facility:
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China,
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5.2. Subject Device

Manufacturer	: Tenscare Limited
Trade/Device Name	: Unipro (K-UNIPRO-USA)
510(k) Number	: K232441
Device Classification Name	: Stimulator, Nerve, Transcutaneous, for pain relief
Common Name:	: For the TENS/MIC system-TENS device For the EMS system-Powered Muscle Stimulators For the IF system-interferential Stimulator
Classification Name	: **For TENS / MIC system** Stimulator, Nerve, Transcutaneous, for Pain Relief - GZJ **For EMS system** Powered Muscle Stimulator - IPF **For IF system** Interferential current therapy - LIH
CFR Regulation Number	: 21 CFR 882.5890 and 21 CFR 890.5850
Product Code	: GZJ, IPF, LIH
FDA Device Classification	: Class II

5.3. Predicate Devices

5.3.1. Predicate Device

Manufacturer	: EasyMed Instruments Co., Ltd
Trade/Device Name	: Ultima NEO
510(k) Number	: K120054
Device Classification Name	: Stimulator, Nerve, Transcutaneous, for pain relief
Regulation Description	: Transcutaneous Electrical Nerve Stimulator for Pain Relief
CFR Regulation Number	: 21 CFR 882.5890 and 21 CFR 890.5850
Product Code	: GZJ, IPF, LIH
FDA Device Classification	: Class II
Device Type ID	: 3755

5.4. Device Description

Unipro is a non-invasive, non-sterile, reusable medical device which is intended to be used in both the hospital and home healthcare environment. It is a microprocessor controlled, non-implantable, portable neuromuscular electrical stimulator which is powered by a built in Li-ion rechargeable battery.

Unipro is a multitherapy unit that combines the treatment capabilities of TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscle Stimulation), MIC (Microcurrent Stimulation) and IFT (Interferential Therapy). The mode selection button on device will enable the user to switch between different modes (TENS, EMS I, EMS II, EMS III, or massage). Each time the user changes the mode or

program, the intensity level will revert to zero. This is a safety feature to alleviate any sudden feeling of a surge, as each program gives a different sensation.

Unipro Case L (large) features a white ABS case with a white silicone button pad and white power button. Power button is located on the right-hand side of the device. The hardware features a black perimeter border and black LCD display. Charging cable and lead inserts are located on the bottom of the device.

Unipro is supplied with self-adhesive electrodes which attach to the control unit via lead wires. A gentle electrical current is sent to underlying nerves and muscle groups via these electrodes applied on the skin to relieve pain. Placement of the electrode pads of the device depends on the selected device mode (TENS, EMS, IFT2, IFT4, MIC). For TENS, the easiest way is to apply the electrode pads around/near the source of the pain. For EMS, place two electrode pads over the bulk of the muscle, with one electrode over the muscle's motor point. For IFT2, electrodes should be placed either side of the area of pain and for IFT4, the pads need to apply in positions so that the signals from each channel cross over the point to be treated. Finally, for MIC, the electrode pads should be placed in such a way that a straight line between them passes through the problem area.

The subject device has no fixed shelf life. The machine will often last for more than 5 years but is warrantied for 2 years. As it is an electronic device, it must not be disposed of as general, domestic waste and must comply with FDA regulation and environmental protection rules for safe disposal of electronic waste.

An unopened pack of electrode pads is intended to last up to two years, which may vary following exposure to low humidity or high temperatures. Once used, the electrode pads are expected to last 12-20 applications, depending on skin condition and humidity. The electrode pads can then be disposed of as standard domestic waste. The subject device and associated accessories are supplied non-sterile.

5.5. Indication For Use/Intended Use

TENS stands for Transcutaneous Electrical Nerve Stimulation. The Unipro TENS system is used to provide symptomatic pain relief for chronic, acute or post-operative pain.

EMS stands for Electrical Neuromuscular Stimulator. The Unipro EMS system is indicated for:

- Relaxation of muscle spasm
- Increasing local blood circulation and muscle re-education
- Prevention or retardation of disuse atrophy
- Prevention of venous thrombosis of the calf muscles immediately after surgery
- Maintaining or increasing range of motion.

MIC stands for Microcurrent Stimulation. -The Unipro MIC system is used to provide symptomatic pain

relief for chronic intractable pain, post traumatic pain or post-surgical pain.
IF stands for Interferential Stimulation. The Unipro system is indicated for:

- Symptomatic relief of chronic intractable pain.

5.6. Indication for Use comparison

TABLE 1: Indication For Use Comparison Table

Characteristic	**New Device Unipro**	**Predicate Device Ultima NEO**	**Comparison**
Manufacturer	Tenscare Limited	EasyMed Instruments Co., Ltd	–
510(k) No.	K232441	K120054	–
Indications for Use	TENS stands for Transcutaneous Electrical Nerve Stimulation. The Unipro TENS system is used to provide symptomatic pain relief for chronic, acute or post-operative pain. EMS stands for Electrical Neuromuscular Stimulator. The Unipro EMS system is indicated for: -Relaxation of muscle spasm -Increasing local blood circulation and muscle re-education -Prevention or retardation of disuse atrophy -Prevention of venous thrombosis of the calf muscles immediately after surgery -Maintaining or increasing range of motion. MIC stands for Microcurrent Stimulation. -The Unipro MIC system is used to provide symptomatic pain relief for chronic intractable pain, post traumatic pain or post-surgical pain.	TENS stands for Transcutaneous Electrical Nerve Stimulation. The Ultima NEO TENS system is used to provide symptomatic pain relief for chronic, acute or post-operative pain. EMS stands for Electrical Neuromuscular Stimulator. The Ultima NEO EMS system is indicated for: -Relaxation of muscle spasm -Increasing local blood circulation and muscle re-education -Prevention or retardation of disuse atrophy -Prevention of venous thrombosis of the calf muscles immediately after surgery -Maintaining or increasing range of motion. MIC stands for Microcurrent Stimulation. -The Ultima NEO MIC	Identical

Characteristic	New Device Unipro	Predicate Device Ultima NEO	Comparison
	IF stands for Interferential Stimulation. The Unipro IF system is indicated for: -Symptomatic relief of chronic intractable pain.	system is used to provide symptomatic pain relief for chronic intractable pain, post traumatic pain or post-surgical pain. IF stands for Interferential Stimulation. The Ultima Neo system is indicated for: -Symptomatic relief of chronic intractable pain.	
Intended population	Male and female patients over the age of 21 requiring pain relief for various types of pain, progress their rehabilitation post injury and encourage results from sports training. Target population includes those who fit this criteria with chronic, acute or post-operative pain and/or Musculo-skeletal injuries. The device should not be used by patients: - Under the age of 22 - During first three months of pregnancy - Who have a pacemaker or heart rhythm problems	Male and female patients over the age of 18 years old.	Substantially Equivalent
Class	II	II	Identical
Product code	GZJ, IPF, LIH	GZJ, IPF, LIH	Identical
Regulation number	21 CFR 882.5890 and 21 CFR 890.5850	21 CFR 882.5890 and 21 CFR 890.5850	Identical

5.7. Technological comparison

Table 2: Basic Unit Characteristics Comparison Table

Characteristic	New Device	Predicate Device	Comparison
Device Name/Model	**Unipro**	**Ultima NEO**	
510(k)	K232441	K120054	
Manufacturer	TensCare Ltd	EasyMed Instruments Co., Ltd	
Power Source(s)[1]	3.7V 1500mAh Lithium-ion battery(rechargeable)	3.7V Lithium-ion battery(rechargeable)	No substantial difference
Method of Line current Isolation	Sequential isolation / transformer isolation	Not publicly available	
Average DC current through Electrodes when device is on but no pulses are being applied (μA)	0	0	Identical
Number of Output Modes	4	4	Identical
Number of programs modes	76	41	No substantial difference. Both comply with IEC 60601-1 requirements
Number of Output Channels	2	2	Identical
Timer Range (minutes)	5-90 minutes, constant	10-90 minutes, constant	No substantial difference. Unipro can be set to lower setting
Regulated Current or Voltage?	Current and Voltage	Current and Voltage	Identical
Software/Firmware/ Microprocessor Control?	Yes	Yes	Identical
Automatic No-Load Trip?	Yes (TENS/EMS)	Not publicly available	
Automatic Overload Trip?	No	Not publicly available	
Automatic Shut Off?	Yes	Not publicly available	
User Override Control?	Yes	Not publicly available	
Indicator Display: -On/Off status -Low battery -Voltage/Current level -Time to cut-off	 Yes Yes Yes Yes	 Yes Yes Yes Yes	Identical

Characteristic	New Device	Predicate Device	Comparison
Device Name/Model	**Unipro**	**Ultima NEO**	
Compliance with Voluntary Standards?	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-11 IEC 62304 IEC 60601-1-6 IEC 62366-1 ISO 10993- 5, 10 and 12 ISO 14971 ISO 13485	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-4 IEC 60601-2-10 IEC/EN 62304 ISO 14971 ISO 13485 IC council 93/42/EEC UL 60601-1	Substantial equivalent
Compliance with 21 CFR 890.5850 and 21 CFR 882.5890	Yes	Yes	Identical
Dimensions (mm)	125mm x 62mm x 29.6mm.	123 x 61 x 22mm (excluding belt clip)	Different, the different dimension does not affect the safety and effectiveness.
Weight g	128.5g	160g (including battery)	Different, the different weight does not affect the safety and effectiveness.
Housing Materials and Construction	ABS 757 material	ABS 757 material	Identical
Sterilization	N/A	N/A	Identical

Table 3: Comparison of output specifications

	New Device UniPro	Predicate Device Ultima NEO	Comparison
510(k) No.	K232441	K120054	/

Waveform	TENS/EMS: Symmetrical Bi-phase Rectangular Microcurrent: continuous square unipolar sawtooth unipolar Symmetrical balanced sine wave IFT: Symmetrical balanced sine wave	TENS/EMS Symmetrical Bi-Phase Rectangular Asymmetrical Bi-Phase Rectangular Mono-Phase rectangular Symmetrical Bi-Polar Rectangular Microcurrent: Symmetrical Bi-Phase Rectangular Mono-Phase rectangular IFT: Symmetrical balanced sine wave	No substantial difference - Waveforms are not substantially different in TENS and Microcurrent programs. Ultima NEO consists of three additional waveforms in TENS program. Both comply with IEC 60601-1 requirements. Identical–Waveforms are identical in IFT and EMS programs.
Maximum Output Voltage (V)	TENS/EMS 54V@500Ω 114 V@2 kΩ 116 V@10 kΩ Microcurrent: 0.4V@500Ω 1.56 V@2 kΩ 7.8 V@10 kΩ IFT: 24V@500Ω 34.4 V@2 kΩ 40 V@10 kΩ	TENS/EMS: 73.6V@500Ω 120V@2 kΩ 124V@10kΩΩ Microcurrent: 0.54V@500Ω 2.12V@2 kΩ 10.2V@10 kΩ IFT: 17V@500Ω 30V@2 kΩ 32 V@10 kΩ	No substantial difference. TENS/EMS and MIC voltage values are lower than Ultima NEO. Both comply with IEC 60601-1 requirements. The difference in voltage is proportional to the current (Since the resistance is the same in both product V=IxR). Therefore, poses no further risk or safety concerns.
Maximum Output Current (mA)	TENS/EMS: 108mA@500Ω (200µs) 80mA @500Ω (400µs) 57mA@2 kΩ 11.6 mA@10 kΩ Microcurrent:	TENS/EMS: 147mA@500Ω 60mA@2 kΩ 12.4mA@10kΩ Microcurrent: 1.08mA@500Ω	No substantial difference. Unipro features an amplitude modulation mode, in which waveforms are pre-modulated.

	0.8mA@500Ω 0.78 mA @2 kΩ 0.78 mA @10 kΩ IFT: 48mA@500Ω 17.2mA@2 kΩ 4mA@10 kΩ	1.06mA@2 kΩ 1.02mA@10kΩ IFT/Amplitude Modulation: 34mA@500Ω 15mA@2 kΩ 3.2mA@10kΩ	Unipro MIC amplitude of 0.8mA is significantly smaller than Ultima Neo and therefore poses no further risk or safety concerns. Both comply with IEC 60601-1 requirements.
Pulse Width (μs)	TENS: 50-300 μs EMS: 100-400 μs Microcurrent: 10-200ms IFT: 125 μs	TENS/EMS: 50-400μs Microcurrent: 2-200ms IFT:120-125μs	No substantial difference. Unipro TENS/EMS and IFT pulse width range are within recommended output, both comply with IEC 60601-2-10.
Frequency(Hz)	TENS: 2-150Hz EMS: 10-120Hz Microcurrent: 0.5Hz, 1Hz, 1.5Hz, 2Hz, 3Hz, 4Hz, 5Hz to 50Hz IFT: 2-160Hz (Carrier Frequency: 4000Hz fixed (CH1))	TENS/EMS:1-150Hz Microcurrent:1-150Hz IFT:4000-4160Hz	No substantial difference. The higher frequency offered by Ultima NEO may not provide any additional benefit in treatment. frequency is still within the recommended range. Both comply with IEC 60601-2-10.
Net Charge (μC per pulse)	0.3μC@ 500 Ω	0.4μC@ 500 Ω	No substantial difference - The Charge output is dependent on current and only used to set the pulse width, therefore variation is irrelevant to treatment. Charge per pulse (μC) = pulse width (ms) x current (mA). Both comply with IEC 60601-1 requirements.

Maximum Phase Charge, (µC)	TENS/ EMS: 22.76µC@500Ω Microcurrent: 160µC@500Ω IFT: 2.8µC@500Ω	TENS/ EMS: 21.62µC@500Ω Microcurrent: 220.8µC@500Ω IFT: 5.16µC@500Ω	No substantial difference. Charge per pulse (µC) = pulse width (ms) x current (mA); The Charge is used to set the pulse width, therefore variation is irrelevant to treatment. Both comply with IEC 60601-1 requirements.
Maximum Current Density, (mA/cm²)	TENS/ EMS: 0.8mA/cm^2@500Ω Microcurrent: 0.008mA/cm^2@500Ω IFT: 0.82mA/cm^2@500Ω	TENS/ EMS: 5.88mA/cm^2@500Ω Microcurrent: 0.022mA/cm^2@500Ω IFT: 1.65mA/cm^2@500Ω	No substantial difference - both comply with IEC 60601-1 requirements.
Maximum Power Density, (W/cm²)	TENS/ EMS: 0.0076 W/cm2 Microcurrent: 0.0001049 W/cm2 IFT: 0.02025 W/cm^2	TENS/ EMS 0.0086W/cm^2(150Hz) Microcurrent: 0.012W/cm^2(150Hz) IFT: 0.017W/cm^2	No substantial difference - both comply with IEC 60601-1 requirements.

Rationale for equivalence claim:

The Unipro and the specified equivalent device are intended to combine TENS, IFT, EMS and MIC technologies to assist with management of a range of conditions (as appropriate to the selected technology), including chronic , acute, and post-operative pain as well as muscle training, toning, bulking and re-education.
The devices have a near-identical principle of operation, all involving the administration of the device onto the skin at anatomical locations suitable for the identified clinical problem. All technologies within the devices are extremely well-established in the market and neither the technologies nor their combination in a single device is novel. As will be demonstrated through the information presented in this section, these devices could be used interchangeably for performing the target procedure.

5.8. Labeling comparison:

Unipro labeling is substantially equivalent to the predicate device, Ultima NEO label.

5.9 Summary of Technological Characteristics Compared to the Predicate Devices

Transcutaneous Electrical Nerve Stimulation (TENS), Electrical Muscle Stimulation (EMS), Microcurrent (MIC) and Interferential (IF) system are the technological principles for both the Unipro and the predicate device.

The subject and predicate device are based on the following same technological elements:

- The new device Unipro is a portable electrotherapy device which combines four systems: Transcutaneous Electrical Nerve Stimulation (TENS), Electrical Muscle Stimulation (EMS), Microcurrent (MIC) and Interferential (IF), into one enclosure. These four systems work separately. When one system is working, the others do not work and thus do not affect each other. This feature has been fully guaranteed by the design. The marketed device Ultima NEO is also a portable electrotherapy device which combines four systems: Transcutaneous Electrical Nerve Stimulation (TENS), Electrical Muscle Stimulation (EMS), Microcurrent (MIC) and Interferential (IF), into one enclosure. These four systems work separately. When one system is working, the others do not work and thus do not affect each other. This feature has been fully guaranteed by the design.
- The new device Unipro combines the systems of TENS and EMS into one package. It is also substantial equivalent to the marketed device Ultima NEO, their features and performances in muscle stimulation as well as pain relief therapy are substantially equivalent.
- The designed circuitry of TENS and EMS modes in the new device Unipro is almost the same as the marketed device Ultima NEO. For the TENS and EMS systems, they are very similar in terms of circuit diagrams and same working principle; the marketed device Ultima NEO combines the Microcurrent (MIC) and Interferential (IF) systems into one package, but these systems are worked separately which is same in the Unipro.
- The marketed device Ultima NEO is a device which includes the Microcurrent stimulation system. Microcurrent stimulation can be generated by a very low and relatively long period current. The specification of microcurrent system in Ultima NEO is very similar to that of Unipro MIC system.

- The marketed device Ultima NEO is an interferential stimulator which generates the real-sine waves of electrical current. The specification of Ultima NEO is very similar to that of Unipro IF system.
- The new device Unipro is designed and combined the Interferential (IF) and Micro-current (MIC) systems based on the design of Ultima NEO.
- The new device Unipro is of the same ranges of parameters as those of marketed device Ultima NEO.
- The software of the new device Unipro can be divided into four parts: the first for TENS system, the second for EMS system, the third for MIC system, and the four one for IF system. First of all, the part of software for TENS system of the new device Unipro is only a subset of that of the marketed device Ultima NEO. Secondly, the considerations on safety, effectiveness and reliability in Ultima NEO are also introduced into the EMS system of the new device; While the part of software for EMS system of the new device Unipro is almost the same as that of the marketed device Ultima NEO, by applying almost the same control methods for muscle contraction-relaxation. In other word. the TENS and EMS systems of the new device Unipro are almost the same as those of the marketed device Ultima NEO. Thirdly, the part of software for Microcurrent (MIC) system of the new device Unipro is very similar to that of the marketed device Ultima NEO. For the last, the part of software for Interferential (IF) system of the new device Unipro is very similar to that of the marketed device Ultima NEO.
- The accessories of the new device Unipro are similar to those of Ultima NEO, the marketed device.
- Both the new device Unipro and the marketed device Ultima NEO are passed the same tests of applicable recognized international consensus standards.

5.10 Summary of Non-Clinical Performance Testing as Basis for Substantial Equivalence

Unipro has undergone extensive bench testing to provide evidence that its mechanical, electrical and software properties are substantially equivalent to the predicate devices, Ultima NEO (K120054). Both Subject and Predicate devices are provided non-sterile, have comparable operations and technology. The design of Unipro does not introduce any new risks.

5.11 Summary of Clinical Testing as Basis for Substantial Equivalence

No clinical testing was considered necessary.

Tenscare conducted a formal review of published research and clinical evaluation on the use of TENS, EMS, IFT and MC in pain relief for chronic, acute, or post-operative pain as well as muscle training, toning, bulking and re-education to establish evidence of the safety and effectiveness of these settings for this Indicated Use and electrode positions.

5.12 Conclusions

TensCare Ltd considers Unipro to be substantially equivalent to the predicate device Ultima NEO (K120054). This conclusion is based upon the devices' similarity in principles of operation, technology, materials, biological, clinical characteristics as well as indications for use.

Any identified differences between the Unipro and equivalent device are minor and of no consequence to safety or performance; most differences are based on commercial decisions and/or are intended to optimise patient comfort and user experience without altering efficacy. Access to data is sufficient to provide the manufacturer with sufficient information about the equivalent devices to support an equivalence claim, since the main data required to form a claim of equivalence relates to technical aspects of the devices (which are technical settings and performance parameters, details of which are available in the public domain) and other information (such as indications/contraindications and mode of action) which are also available in the public domain.

Therefore, the information submitted to the FDA for the Unipro does not raise new questions about safety or effectiveness and demonstrates with reasonable assurance based on stablished controls that the device is at least as safe and effective as a legally marketed device.