K163166 – 510(k) Summary

I. SUBMITTER

EASYWELL BIOMEDICALS INC.
Suite 2, 2F, No.9, Jhanye 1st Rd., Hsinchu Science Park, 30078 Hsinchu, TAIWAN
Phone：+886-3-666-9596
FAX： +886-3-666-9697
Contact Person：Richard Hsieh
Date：Oct. 04, 2016

II. DEVICE

Trade/Device Name: Easywell TENS System (TENS only), Easywell TENS System (TENS and Heat)
Common Name: Transcutaneous Electrical Nerve Stimulator (TENS)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulation Class: Class II
Product Code: NUH

III. PREDICATE DEVICE

Omron: Heat Pain Pro (K160115)

IV. DEVICE DESCRIPTION

The EASYWELL TENS System is a Transcutaneous Electrical Nerve Stimulation (TENS) set consisting of a stimulator console, an electrode patch, gel pads and an AC/DC adaptor, used for pain relief. There are two models available over-the-counter- (1) TENS only, and (2) a combination of TENS and heat for a warming sensation up to 41.0°C (105.8°F). The TENS session lasts 15 minutes with 3 stages of varying frequencies.

The stimulator console is wearable, weights 32g, with one micro-USB port and one LED light indicator. It has two buttons- "+" button to turn on the stimulator console and to increase the TENS intensity level by 1 (10 intensity levels); "-" button to decrease the TENS intensity or turn off the stimulator console when it's pressed for 3 seconds. The green LED light is lit up when the stimulator console is activated. The AC/DC adaptor can be connected to the micro-USB port to recharge the Li-ion battery.

The electrode patch is covered by polyester and nylon blended textile and can be connected

to the stimulator console via connectors. Patches with varying shapes and sizes are available to fit different and anatomical positions. Carbon fiber is embedded between the electrode and textile to provide heat conductance and far infrared radiation (model EETTA00 and EETTL00 to provide TENS and heat).

The gel pads are applied to the electrode surface. They are directly in contact with the skin and made from medical grade electrically conductive hydrogel. They comply with ISO 10993-5 biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity and ISO 10993-10 biological evaluation of medical devices- Part 10: tests for irritation and skin sensitization.

The AC/DC adapter is medical graded which complies with IEC 60601-1 and IEC 60601-1-2

V. INTENDED USE

The relief of pain associated with sore or aching muscles due to strain from exercise or normal household work activities.

VI. CONFORM STANDARDS

EASYWELL TENS System conforms to the following standard:

1. AAMI_NS4: 2013 Transcutaneous electrical nerve stimulators
2. IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
3. IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
4. IEC 60601-1-11:2015 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
5. IEC 60601-2-10: 2012 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
6. ISO 10993-1: 2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
7. ISO 10993-5: 2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
8. ISO 10993-10: 2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
9. IEC 62304: 2006 Medical device software -- Software life cycle processes
10. EN/ISO 14971: 2012 Medical devices. Application of risk management to medical devices

11. IEC/EN 62133:2013 Safety Test Standard of Li-Ion Cell and Battery
12. UN38.3 Testing-Safety Precautions for the Transportation of Lithium Batteries

VII. Similarities/Differences of the proposed candidate device when compared to the predicate

Omron Heat Pain Pro (K160115)

The subject EASYWELL TENS System is substantially equivalent to the predicate Heat Pain Pro (K160115) marketed by Omron Healthcare, Inc. with similar indications for use. The subject EASYWELL TENS System is intended for pain relief with sore or aching due to exercise or normal household work activities. The predicate Heat Pain Pro is intended for relief of pain associated with sore or aching, muscles of the lower back, arms, legs, shoulder, or foot due to strain from exercise or normal household work activities.

Both the subject EASYWELL TENS System and predicate Heat Pain Pro are available Over-the-Counter (OTC).

Both the subject EASYWELL TENS System and the predicate Heat Pain Pro have similar design specifications. Both use microprocessor technology to control the device and use Lithium-Ion battery as the power source. Both are rechargeable, can automatic shut off, and use the electrode patch with hydrogel.

Both the subject EASYWELL TENS System and the predicate Heat Pain Pro have similar output parameters. Both have 1 output channel. The subject EASYWELL TENS System provides TENS therapy on models EETTA00 and EETTL00, and, provides TENS therapy with heat on models EETTA01 and EETTL01; the predicate Heat Pain Pro provides TENS therapy and TENS therapy alternating heat. Both have similar heat temperature range, the subject EASYWELL TENS System conducts heat at maximum 41°C on models EETTA01 and EETTL01 and the predicate Heat Pain Pro conducts heat at maximum 43°C. Both have biphasic rectangular waveform shape. The subject EASYWELL TENS System has timer range 15 minutes and it's repeatable to extend the range, the predicate Heat Pain Pro has timer range 30 minutes.

The subject EASYWELL TENS System and the predicate Heat Pain Pro comply with the same standards including IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11 and IEC 60601-2-10. The subject EASYWELL TENS System also complies with AMMI NS4.

The similarities between the subject EASYWELL TENS System and the predicate Heat Pain Pro are compared in table 1.

Table 1 Comparison with the predicate Heat Pain Pro (K160115)

Feature		Subject		Predicate
510(k) Number		-		K160115
Manufacturer		EASYWELL Biomedicals, Inc.		Omron Healthcare, Inc.
Trade Name		EASYWELL TENS System		Omron Heat Pain Pro
Model Name		EETTA00 EETTL00 (TENS Only)	EETTA01 EETTL01 (TENS and Heat)	PM311
Indications for Use		The EASYWELL TENS System is intended for: The relief of pain associated with sore or aching muscles due to strain from exercise or normal household work activities.		The Omron Heat Pain Pro is intended for: The relief of pain associated with sore or aching, muscles of the lower back, arms, legs, shoulder, or foot due to strain from exercise or normal household work activities.
Type of Use		Over-the-Counter (OTC)		Over-the-Counter (OTC)
Design Specification	Controller	Microprocessor		Microprocessor
	Power Source	Lithium-Ion battery		Lithium-Ion battery
	Rechargeable	Yes		Yes
	Automatic Shut Off	Yes		Yes
	Electrode Patch/ Gel Pad	Electrode Patch with Hydrogel		Electrode Patch with Hydrogel
Output Parameter	Number of output channels	1 Channel		1 Channel
	Output Modes	TENS Therapy only	TENS Therapy with HEAT	1) TENS Therapy Only 2) TENS Therapy alternating HEAT
	Heat Temperature	N.A.	41°C Maximum	43°C Maximum
	Waveform Shape	Biphasic Rectangular		Biphasic Rectangular
	Timer Range	15 minutes		30 minutes
Compliance with Standards		IEC60601-1 IEC60601-1-2		IEC60601-1 IEC60601-1-2

			IEC 60601-1-11 IEC60601-2-10 AAMI NS4	IEC 60601-1-11 IEC60601-2-10
Performance and Specifications	Max. Output Voltage	@500Ω	58.8V	67.2V
		@2KΩ	94V	86.0V
		@10KΩ	119V	95.9V
	Max. Output Current	@500Ω	117.6mA	134.2mA
		@2KΩ	45.5mA	45.0mA
		@10KΩ	11.9mA	9.6mA
	Duration of primary phase		132μs	32μs
	Pulse Duration@500Ω		220μs	96μs
	Frequency		2.2 to 34.7Hz	1 to 99Hz
	Net Charge @500Ω (per pulse)		0μC	0μC
	Maximum Phase Charge @500Ω		15.5μC	4.3μC
	Active Surface Area for each Electrode (cm^2)		1) EW-P000-G Standard 30 2) EW-P000-L Lower Back 60	25
	Maximum Current for each Electrode @500Ω(mA)		1) EW-P000-G Standard 117.6 2) EW-P000-L Lower Back 117.6	134.2
	Maximum Charge Density for each Electrode @500Ω (mA/cm^2)		1) EW-P000-G Standard 3.92 2) EW-P000-L Lower Back 1.96	5.38
	Maximum Power Density for each Electrode @500Ω (mW/cm^2)		1) EW-P000-G Standard 230.5 2) EW-P000-L Lower Back 115.2	361.3

Substantial Equivalence:

EASYWELL TENS System has the same intended use, principles of operation, and similar technological characteristics as predicate devices. Moreover, bench testing contained in this submission and clinical evaluation report supplied demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the EASYWELL TENS System is substantially equivalent to the predicate devices.