DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 6, 2016

Xanacare Technologies, LLC
% Charles Hart
Principal Consultant
Hart Consulting LLC
2964 Redhaven Way
Littleton, Colorado 80126-5595

Re: K160246
Trade/Device Name: Simulcare II™
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ, ILY, ISA
Dated: August 31, 2016
Received: August 31, 2016

Dear Mr. Hart:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Hoffmann -A

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160246

Device Name
SimulCare II™

Indications for Use *(Describe)*
The SimulCare II™ is intended for the temporary relief of minor muscle and joint pain, promoting the relaxation of muscle tissue, temporarily increasing local blood circulation, symptomatic relief and management of chronic intractable pain, and adjunctive relief of post-surgical or post-traumatic 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date prepared:	06 Oct 2016		
Applicant:	Xanacare Technologies, LLC		
Contact person:	Thomas C. Siirola Manager & CEO Xanacare Technologies, LLC Denver, Colorado 80237-1857 Phone: (720) 554-9262 Fax: (720) 554-9264 Email: tcsiirola@xanacare.com		
Trade name:	SimulCare II™		
Common name:	Multi-function Therapeutic Device	Class:	2
Classification name:	Transcutaneous Electrical Nerve Stimulator for Pain Relief	Product code:	GZJ, ILY & ISA
Predicate devices:	K083202, K081141		

Device description:
The SimulCare II Multi-function Therapeutic Device is modified from the SimulCare and ComboCare 2000 devices previously cleared under 510(k)s K083202 & K081141 and includes improved interface features, EMI filters, additional audible alarm and battery monitoring circuit drain prevention.

Indications for use:
The SimulCare II Multi-function Therapeutic Device is intended for the temporary relief of minor muscle and joint pain, promoting the relaxation of muscle tissue, temporarily increasing local blood circulation, symptomatic relief and management of chronic intractable pain, and adjunctive relief of post-surgical or post-traumatic pain.

Shipping & Storage:
The packaged device will withstand normal shipping and storage environments and labeling shall meet 21CFR 801, EN 1041, and ISO 15223.

Non-clinical tests submitted or relied upon:	Safety & EMC Testing
Clinical tests submitted or relied upon:	None
Substantial equivalence conclusion:	The SimulCare II Multi-function Therapeutic Device is substantially equivalent to the legally marketed FDA cleared predicate devices, based on intended use, materials, and design. The proposed devices do not introduce new issues of safety or effectiveness.

Technological Characteristics Comparison Table

The following table shows the significant similarities and no differences between the proposed device (this submission) and the predicate Devices (K083202 & K081141):

Device Description	**SimulCare II™**	**SimulCare™**	**ComboCare 2000™**	**Differences**
Manufacturer	**Xanacare Technologies**	**Xanacare Technologies**	**Xanacare Technologies**	
510(k) Number	**(This Submission)**	**K083202**	**K081141**	
Intended Use	The SimulCare II Multi-function Therapeutic Device is intended for the temporary relief of minor muscle and joint pain, promoting the relaxation of muscle tissue, temporarily increasing local blood circulation, symptomatic relief and management of chronic intractable pain, and adjunctive relief of post-surgical or post-traumatic pain.	The SimulCare Multi-function Therapeutic Device is intended for the temporary relief of minor muscle and joint pain, promoting the relaxation of muscle tissue, temporarily increasing local blood circulation, symptomatic relief and management of chronic intractable pain, and adjunctive relief of post-surgical or post-traumatic pain.	The ComboCare 2000 Multi-function Therapeutic Device is intended for the temporary relief of minor muscle and joint pain, promoting the relaxation of muscle tissue, symptomatic relief and management of chronic intractable pain, and adjunctive relief of post-surgical or post-traumatic pain.	Predicate device ComboCare 2000™ K081141 did not state an intended use for temporarily increasing local blood circulation.

Device Description	SimulCare II™	SimulCare™	ComboCare 2000™	Differences
Manufacturer	Xanacare Technologies	Xanacare Technologies	Xanacare Technologies	
510(k) Number	(This Submission)	K083202	K081141	
Design	Portable, lightweight, rechargeable unit consisting of a hand-held controller with digital control of stimulation parameters and an attached flexible pad that produces battery-charged therapy consisting of red light emitting diodes, infrared light emitting diodes, micro current, macro current (E-stim), permanent magnets and vibratory massage.	Portable, lightweight, rechargeable unit consisting of a hand-held controller with analog control of stimulation parameters and an attached flexible pad that produces battery-charged therapy consisting of red light emitting diodes, infrared light emitting diodes, micro current, macro current (E-stim), permanent magnets and vibratory massage.	Portable, lightweight, rechargeable unit consisting of a hand-held controller with analog control of stimulation parameters and an attached flexible pad that produces battery-charged therapy consisting of red light emitting diodes, infrared light emitting diodes, micro current, macro current (E-stim), and vibratory massage.	Predicate devices SimulCare™ K083202 and ComboCare 2000™ K081141 utilized analog control of stimulation parameters, while the proposed SimulCare II™ device utilizes digital control of stimulation parameters.

Device Description	SimulCare II™	SimulCare™	ComboCare 2000™	Differences
Manufacturer	**Xanacare Technologies**	**Xanacare Technologies**	**Xanacare Technologies**	
510(k) Number	**(This Submission)**	**K083202**	**K081141**	
Material	All patient contacting materials used in the device are identical to those similarly used in other FDA cleared or 510(k) exempt devices, in formulation and processing, and no other chemicals have been added (e.g. plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).	All patient contacting materials used in the device are identical to those similarly used in other FDA cleared or 510(k) exempt devices, in formulation and processing, and no other chemicals have been added (e.g. plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).	All patient contacting materials used in the device are identical to those similarly used in other FDA cleared or 510(k) exempt devices, in formulation and processing, and no other chemicals have been added (e.g. plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).	Predicate devices SimulCare™ K083202 and ComboCare 2000™ K081141 utilized Conductive Gel, while the proposed SimulCare II™ device utilizes Conductive Spray.
Chemical Composition	Pad cloth material = Nylon Jersey Fabric (latex free)	Pad cloth material = Nylon Jersey Fabric (latex free)	Pad cloth material = Nylon Jersey Fabric (latex free)	
	IR LED lens & Red LED lens = Water Clear Epoxy	IR LED lens & Red LED lens = Water Clear Epoxy	IR LED lens & Red LED lens = Water Clear Epoxy	
	Conductive (TENS) electrode contacts = Chrome plated brass	Conductive (TENS) electrode contacts = Chrome plated brass	Conductive (TENS) electrode contacts = Chrome plated brass	
	Static Magnetic Discs = Ferrite	Static Magnetic Discs = Ferrite	None	
	Conductive Spray = Water Soluble, Clear Green, Odorless, Aqueous Liquid	Conductive Gel = Water Soluble, Clear Green, Odorless, Aqueous Liquid	Conductive Gel = Water Soluble, Clear Green, Odorless, Aqueous Liquid	
Energy Source	Charged Batteries	Charged Batteries	Charged Batteries	

13 Substantial equivalence discussion

Substantial Equivalence Comparison Table #1

The following table shows the significant similarities and differences between the Xanacare SimulCare II (this submission) and the predicate products, Xanacare SimulCare (K083202) and ComboCare 2000 (K083202:

Device Description **510(k) Number:**	**SimulCare II™** **(This submission)**	**SimulCare™** **K083202**	**ComboCare 2000™** **K081141**
Available Features:	3 Modes	3 Modes	3 Modes
• Infrared Light	Pulsed infrared light emitting diodes (LED)	Pulsed infrared light emitting diodes (LED)	Pulsed infrared light emitting diodes (LED)
• Red Light	Pulsed red light emitting diodes (LED)	Pulsed red light emitting diodes (LED)	Pulsed red light emitting diodes (LED)
• Magnetic	Static magnetic field.	Static magnetic field.	None
• TENS	Transcutaneous electrical nerve stimulator	Transcutaneous electrical nerve stimulator	Transcutaneous electrical nerve stimulator
• Vibrator	Vibratory massage	Vibratory massage	Vibratory massage
• Laser	None	None	None
Treatment Times:	10-12 minute treatment sessions, 1 to 3 times a day as necessary.	10-12 minute treatment sessions, 1 to 3 times a day as necessary.	10-12 minute treatment sessions, 1 to 3 times a day as necessary.
Electrical Power Source:	4 Rechargeable AA NiMH batteries	4 Rechargeable AA NiMH batteries	4 Rechargeable AA NiMH batteries
LED Pulse Width	75 milliseconds, 5-12 Hz	75 milliseconds, 5-12 Hz	75 milliseconds, 5-12 Hz
IR LED Power	< 45 mW per LED	< 45 mW per LED	< 45 mW per LED
IR LED Wavelength	870 nm	870 nm	870 nm
No. of IR LEDs	24 LEDS (regular pad) / 48 LEDs (large pad)	24 LEDS (regular pad) / 48 LEDs (large pad)	24 LEDS (regular pad) / 48 LEDs (large pad)
Red LED Power	~ 10,000 mcd (millicandela) per LED	~ 10,000 mcd (millicandela) per LED	~ 10,000 mcd (millicandela) per LED
Red LED Wavelength	640 nm	640 nm	640 nm
No. of RED LEDs	32 LEDs (regular pad) / 64 LEDs (large pad)	32 LEDs (regular pad) / 64 LEDs (large pad)	32 LEDs (regular pad) / 64 LEDs (large pad)
Types of Magnets	4 permanent magnets	4 permanent magnets	None
Magnetic Strength	300 – 475 Gauss	300 – 475 Gauss	None
Vibrator	Miniature pancake motor(s)	Miniature pancake motor(s)	Miniature pancake motor(s)

Substantial Equivalence Comparison Table #2

The following table shows the significant similarities and differences between the Xanacare SimulCare II (this submission) and the predicate products, Xanacare SimulCare (K083202) and ComboCare 2000 (K083202):

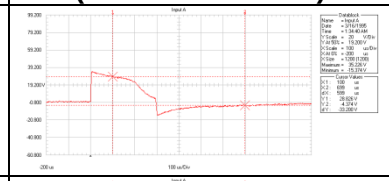
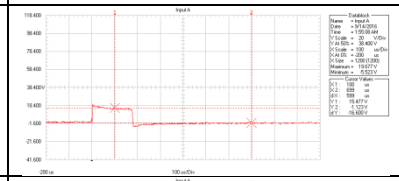
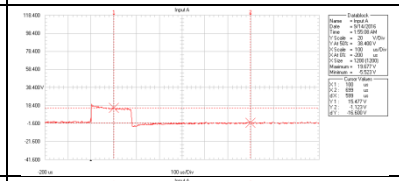
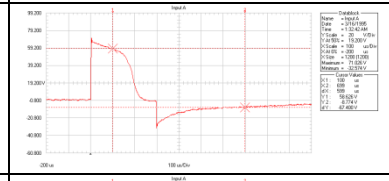
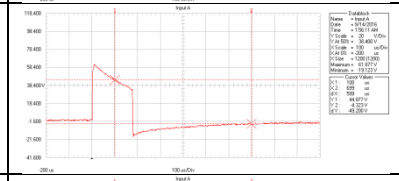
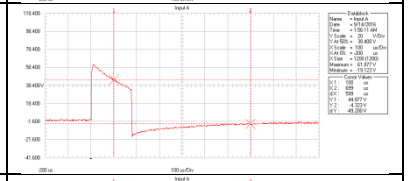
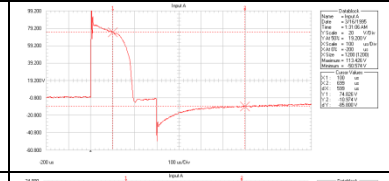
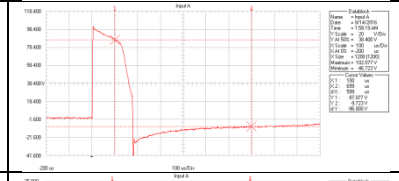
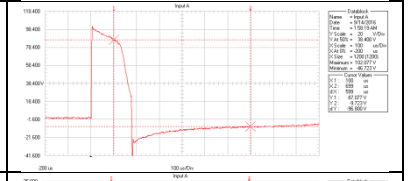
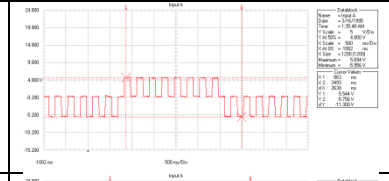
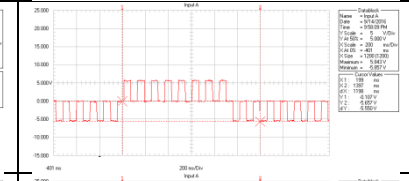
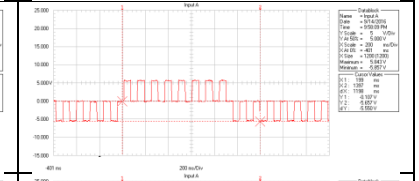
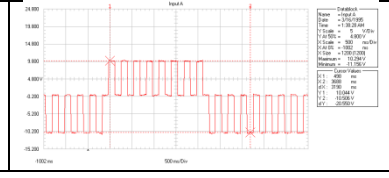
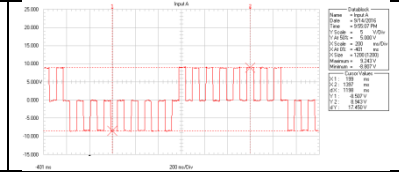
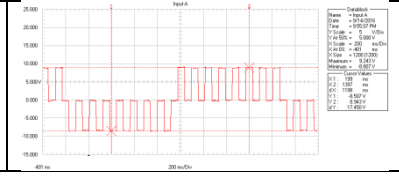
Device Description **510(k) Number:**	**SimulCare II™[1]** **(This submission)**	**SimulCare™** **K083202**	**ComboCare 2000™** **K081141**
Number of Channels	1	1	1
Maximum Output Current [2]	0-40 mA / 500 Ω load (E-stim mode)	0-40 mA / 500 Ω load (E-stim mode)	0-40 mA / 500 Ω load (E-stim mode)
	0-14.4 mA / 500 Ω load (microcurrent mode)	0-14.4 mA / 500 Ω load (microcurrent mode)	0-14.4 mA / 500 Ω load (microcurrent mode)
Maximum Output Voltage [2]	0-30 V / 1 KΩ load (E-stim mode)	0-30 V / 1 KΩ load (E-stim mode)	0-30 V / 1 KΩ load (E-stim mode)
	0-9.3 V / 1 KΩ load (microcurrent mode)	0-9.3 V / 1 KΩ load (microcurrent mode)	0-9.3 V / 1 KΩ load (microcurrent mode)
Pulse Rate / Frequency [3]	Fixed at 68 pps/Hz, (E-stim mode)	Fixed at 68 pps/Hz, (E-stim mode)	Fixed at 68 pps/Hz, (E-stim mode)
	Fixed at 3.5 pps/Hz, (microcurrent mode)	Fixed at 3.5 pps/Hz, (microcurrent mode)	Fixed at 3.5 pps/Hz, (microcurrent mode)
Tens Pulse Width	200 microseconds	200 microseconds	200 microseconds
Tens Waveform	Asymmetrical Pulse Train ~68 Hz	Asymmetrical Pulse Train ~68 Hz	Asymmetrical Pulse Train ~68 Hz
µTENS Pulse Width	143 milliseconds	62 milliseconds	62 milliseconds
µTENS Waveform	Asymmetrical biphasic square wave changes polarity every 8 cycles for net zero charge (biphasic)	Asymmetrical biphasic square wave changes polarity every 8 cycles for net zero charge (biphasic)	Asymmetrical biphasic square wave changes polarity every 8 cycles for net zero charge (biphasic)

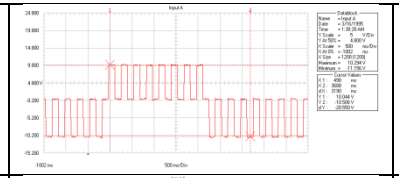
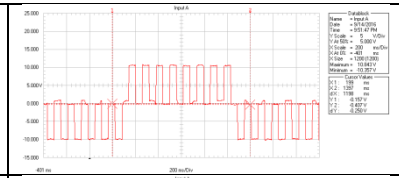
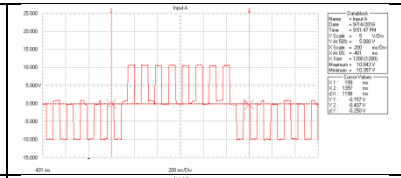
Notes:

[1] SimulCare II Multi-function Therapeutic Device operates in either in E-stim or micro-current mode, depending on switch setting.

[2] The SimulCare II Multi-function Therapeutic Device is constant current output devices. Therefore there output voltage, current and power are dependent upon the load.

[3] Nominal factory settings for the SimulCare II is 72 pps/Hz (E-stim mode) and 8 pps/Hz (micro-current mode).

Device Tracings	SimulCare II™	SimulCare™	ComboCare 2000™	Differences
Manufacturer	Xanacare Technologies	Xanacare Technologies	Xanacare Technologies	
510(k) Number	(This Submission)	K083202	K081141	
TENS@500Ω (E-stim mode)				Predicate devices SimulCare™ K083202 and ComboCare 2000™ K081141 TENS & µTENS Controller outputs identical and are substantially similar to the proposed device SimulCare II™
TENS@2kΩ (E-stim mode)				
TENS@10kΩ (E-stim mode)				
µTENS@500Ω (microcurrent mode)				
µTENS@2kΩ (microcurrent mode)				

µTENS@10kΩ (microcurrent mode)				
TENS Train (E-stim mode)