September 15, 2018

Pfizer Inc.
% Siping Yuan
R.A. Specialist
Shenzhen Dongdixin Technology Co., Ltd
No. 3 Building, Xilibaimang Xusheng Industrial Estate
Nanshan, Shenzhen, Cn 518108

Re: K181102
Trade/Device Name: ThermaCare Quick Therapy TENS, TC001
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NYN
Dated: April 20, 2018
Received: April 26, 2018

Dear Siping Yuan:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Pamela D. Scott -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181102

Device Name
ThermaCare® Quick Therapy TENS
Model: TC001

Indications for Use *(Describe)*
The device is intended to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities(arm) and lower extremities (leg) due to strain from exercise or normal household work activities. And to be used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

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.

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510(k) SUMMARY

as required by section 21 CFR 807.92

ThermaCare® Quick Therapy TENS

Date of Submission:	04/23/2018
Submitter/510(k) Owner's Name:	Pfizer Inc.
Address:	235 East 42nd Street, New York, New York 10017, USA
Contact Person:	Nicola Romano
E-mail:	nicola.romano@pfizer.com
Tel:	973-660-5858
Correspondent's Name:	Shenzhen Dongdixin Technology Co., Ltd.
Address:	No.3 Building Xilibaimang Xusheng Industrial Estate, Nanshan, Shenzhen, CHINA 518108
Correspondent Contact:	Siping Yuan
E-mail:	ra@dundex.com
Tel:	+86(755) 27652471
FAX:	+86(755) 27652674

1. Proposed Device:

Device Name: ThermaCare® Quick Therapy TENS

Model: TC001

Device classification Name:	Stimulator, Nerve, Transcutaneous, Over-The-Counter
Regulation Description:	Transcutaneous electrical nerve stimulator for pain relief
Regulation Medical Specialty:	Neurology
Review Panel:	Neurology
Regulation Number:	882.5890
Product Code:	NUH
Device Class:	II

Device classification Name:	Stimulator, Electrical, Transcutaneous, For Arthritis
Regulation Description:	Transcutaneous electrical nerve stimulator for pain relief.
Regulation Medical Specialty:	Neurology
Review Panel:	Neurology
Regulation Number:	882.5890
Product Code:	NYN
Device Class:	II

2. Predicate Device:

Legally Marketed Device:	Wireless Pain Relieve Device LT5018C
510(k) Number:	K173462
Manufacturer:	Shenzhen Dondixin Technology Co., Ltd.

3. Description of Proposed Device:

The ThermaCare® Quick Therapy TENS device is a wireless, two channels wearable electrotherapy device that is designed to alleviate chronic muscle and joint pain on multiple body locations. It delivers TENS (Transcutaneous Electrical Nerve Stimulation) technology through the simple, convenient use of the dedicated APP (iOS or Android) or remote control. Reusable, self-adhesive pads allow for discreet and convenient placement on multiple pain locations on the body. The ThermaCare® Quick Therapy TENS contains 23 TENS programs. It is designed to be used at home, by adults of all genders.

The ThermaCare® Quick Therapy TENS device contains one main TENS unit which is rechargeable and one remote control which is powered by 2 AAA batteries. The pads with attached TENS unit can then be applied to intact skin at the desired location for pain relief. Control of the ThermaCare® Quick Therapy TENS device is completed through the available TENS APP (iOS or Android)or remote control. The

communication is done via Bluetooth Low Energy.

The device will be packaged with an Instruction Manual which provides details on setting up the device for use, installing of the App, setting and controlling therapy programs, and troubleshooting. The ThermaCare® Quick Therapy TENS consists of the following elements:

- Main device: generates the TENS pulses; connects to the electrode; controlled by APP on smart phone and remote control.
- Electrodes: Self-adhesive re-usable hydrogel electrodes connects to the device.
- APP on mobile device: The APP controls the functions of the main device via a Bluetooth (4.0) Low Energy connection between the mobile device and the main device.
- Remote control: The remote control controls the functions of the main device via a Bluetooth (4.0) Low Energy connection between the remote control and the main device.
- Adapter (optional): for charging the battery unit via a micro-USB socket which connected with the adapter, and insert the adapter to the supply mains.

4. Proposed Device Intended for Use Statement:

Device Name: ThermaCare® Quick Therapy TENS, Model: TC001

Indications for Use:

The device is intended to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities(arm) and lower extremities (leg) due to strain from exercise or normal household work activities. And to be used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

5. Technological Characteristics and Substantial Equivalence

Both the TC001 and Predicate Device utilize the application of electrical current through electrodes placed on the skin for pain control. The impulses are generated by the device and delivered through electrodes on the skin in direct proximity to the (painful) muscles to be stimulated.
Basic technological characteristics, new device vs. Predicate device.

Table 1：Substantial Equivalence Comparison Table

		New device	Predicate device	S.E. Discussion
1	**510K#**	**To be assigned**	**K173462**	**N/A**
2	Device Name and Model	ThermaCare® Quick Therapy TENS Mode: TC001	Wireless Pain Relieve Device Mode: LT5018C	**N/A**
3	Applicant	Pfizer Inc.	Shenzhen Dongdixin Technology Co., Ltd	N/A
4	Manufacturer	Shenzhen Dongdixin Technology Co., Ltd	Shenzhen Dongdixin Technology Co., Ltd	Same
5	Intended for use	TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back , upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. And to be used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.	TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. And to be used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. EMS: The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.	Applicant is not pursuing EMS use statement for the new device.
6	Power Source	DC 3.7V Li-ion Battery(main device) DC 3.0V, 2 x AAA Batteries (Remote control)	DC 3.7V Li-ion Battery(main device) DC 3.0V, 2 x AAA Batteries (Remote control)	Same
	-Method of Line	N/A	N/A	Same

	current isolation			
	- Patient Leakage Current (μA) -Normal condition -Single fault condition	 d.c:0 uA. a.c.:29 uA max d.c:0 uA. a.c.:69 uA max	 0uA 2.0uA	Different, TC 001 have been evaluated and passed the test according to the requirement of IEC 60601-1.
7	Average DC current through electrodes when device is on but no pulses are being applied (μA)	0	0	Same
8	Number of Output Modes	1 (TENS)	2 (TENS/EMS(including MASSAGE))	Different, TC001 only has TENS mode and TC001 remove indications for use of EMS mode accordingly.
9	Number of Output Channels			
	Synchronous or Alternating?	Alternating	N/A	Different, TC001 has two channels and each channel outputs have been evaluated and passed the test according to the requirement of IEC 60601-2-10.
	Method of Channel Isolation	By Electrical Circuit and Software	N/A	Different, TC001 has two channels and have been evaluated and passed the test according to the requirement of IEC 60601-1.
10	Regulated Current or Regulated Voltage?	Current control	Current control	Same
11	Software/Firmware/ Micro processor Control?	Yes	Yes	Same

12	Automatic Overload Trip	Yes	Yes	Same
13	Automatic No Load contact Trip	Yes	Yes	Same
14	Automatic Shut off	Yes	Yes	Same
15	User Override Control?	Yes Power [on/off] button on the device Power [on/off] button on the remote control [Stop session] button in the APP software	Yes Power on/off button on the device Power on/off on the remote control Power on/off in the APP software	Same function
16	Indicator Display:			
	On/Off Status?	Yes	Yes	Same
	Low Battery?	Yes	Yes	Same
	Voltage/ Current Level?	Yes	Yes	Same
17	Timer Range (minutes)	5-30 minutes	30 minutes	Different, new device have been evaluated and passed the test according to the requirement of IEC 60601-2-10. User can set the treatment time according their needs.
18	Weight (grams.)	32grams (Main device) 55 grams (Remote control without batteries)	36grams (Main device) 65 grams (Remote control)	Different, the new device have been evaluated and passed the testing according to the requirement of IEC 60601-1.
19	Dimensions (cm.) H*W * L	80.5(L)x45(W)x13.5(H)mm (Main device) 127(L)x48.6(W)x24.4(H)mm (Remote control)	360(L)x59(W)x11.5(H)mm (Main device) 115(L)x53(W)x25(H)mm (Remote control)	
20	Housing Materials &	ABS	ABS	Same

	Construction			
21	Compliance with 21 CFR 898	Yes	Yes	Same
22	Compliance with Voluntary Standards?	IEC 60601-1:2005+A1:2012 IEC 60601-1-2:2014 IEC 60601-2-10: 2012 IEC60601-1-11: 2015 ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2010	IEC 60601-1:2005+A1:2012 IEC 60601-1-2:2014 IEC 60601-2-10: 2012 IEC60601-1-11: 2015 ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2010	Same

Table 2：Output Specification TENS mode

		New device	Predicate device	S.E. Discussion
1	510K#	To be assigned	K173462	N/A
2	Device Name or Program Name	ThermaCare® Quick Therapy TENS Mode:TC001	Wireless Pain Relieve Device Mode:LT5018C	N/A
4	Waveform	Biphasic	Biphasic	Same
5	Shape	Rectangular	Rectangular	Same
6	Max Output Voltage (V) ±20%			
7	500Ω	30.4	31	Similar, the new device have been evaluated and passed the test according to the requirement of IEC 60601-2-10.
8	2kΩ	70	66	
9	10kΩ	70	66	
10	Max Output Current (mA) ±20%			
11	500Ω	60.8	62	Similar, the new device have been evaluated and passed the test according to the requirement of IEC60601-2-10
12	2kΩ	35	33	
13	10kΩ	7	6.6	
14	Pulse Duration	100~200us	150~250us	Similar, the new device have

	(μsec)			been evaluated and passed the test according to the requirement of IEC60601-2-10
15	Frequency (Hz)	2~100Hz	2~100Hz	Same
16	Maximum Phase Charge (uC) 500Ω	24.32	31	Similar, the new device have been evaluated and passed the test according to the requirement of IEC 60601-2-10.
17	Maximum Current Density 500Ω	0.295mA/cm2	0.48mA/cm2	
18	Maximum Average Current (average absolute value), mA, 500Ω	1.22	1.2	
19	Maximum Average Power Density, (mW/cm^2),500Ω	1.8	2.88	

Discussion:

The number of output modes, number of output channels, timer range, weight and dimension of the new device are different from the predicate devices, but the new devices are evaluated and passed the testing according to IEC 60601-1 and IEC 60601-2-10, this difference does not pose any new questions of safety.

The Max Output Voltage/Current, Pulse Duration, Maximum Phase Charge, Maximum Current Density and Maximum Average Power Density are similar with the predicate devices, but the new devices are evaluated and passed the testing according to IEC 60601-2-10, this difference doesn't pose any new questions of safety and effectiveness.

6. Performance Data:

The following performance data are provided in support of the substantial equivalence determination:

6.1 Biocompatibility testing

The biocompatibility evaluation for the TC001 was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process". As dictated by the application and duration of contact with the intact skin, the testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

6.2 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the TC001. The system complies with the IEC 60601-1, IEC60601-1-11 and IEC 60601-2-10 standards for safety and the IEC 60601-1-2 standard for EMC.

For FCC part 15 RADIO FREQUENCY DEVICES, Subpart C—Intentional Radiators.

6.3 Software Verification and Validation Testing

Main device, Remote control and APP software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern.

6.4 Output waveform Testing

For each program, oscilloscope tracing diagrams describing the electrical output waveform was provided to verify the output specifications of the device according to IEC 60601-2-10.

7. Conclusions

The intended use and basic technological characteristics of the ThermaCare® Quick Therapy TENS are equivalent with those of the Predicate device K173462. Any technological differences do not raise new questions regarding safety and effectiveness.