Section 4
510(k) Summary

JAN 2 3 2014

K130666

In accordance with 21 CFR 807.92:

1. Submitter's Information

Khan Kinetic Treatment Device (KKT-M2)

Optima Health Solutions International Corp.
303 – 828 West 8th Street
Vancouver, British Columbia
Canada, V5Z 1E2

Contact: Farhad Ghani
Tel: (604) 266 5338
Fax: (604) 267 0911

2. Name of the Device

Khan Kinetic Treatment Device (KKT-M2)

Common Name: Manipulator Device

Device Classification Name: Manipulator, Plunger-Like Joint

Classification (21CFR 890): Unclassified

3. Legally Marketed Predicate Device:

The (KKT-M2) has the same intended use and indications for use as the previously cleared device (KKT-M1), as well as similar performance and principles of operation. The technological differences between the (KKT-M2) and predicate KKT-M1 device is primarily improvement in design and manufacturing of the device. The device and its components have been thoroughly tested for safety and effectiveness to ensure that no new issues of safety or effectiveness are raised from the design change.

Information on the Predicate Device:

Name: ..... Khan Kinetic Treatment Device (KKT-M1)

Product Code: ..... LXM

510(k) Number: K060043

Marketed by: ..... Optima Health Solutions International Corp.

Address: ..... 303 – 828 West 8th Street
Vancouver, British Columbia
Canada, V5Z 1E2

Establishment Registration No.: 10040107

4. Description of the Device:

The KKT device has been developed for the aid in management of chronic pain. More specifically, conditions of chronic pain arising from structural anomalies such as misalignments and muscle imbalances. Conditions of brain stem irritation as a result of musculoskeletal imbalances that may arise from impact.

Typical conditions treated include: strains to soft tissue surrounding vertebral column, whiplash injuries to the head and neck, and biomechanical dis-relationships of the axial skeleton. This device is not intended to be used in acute situations of pain management.

5. Statement of the Intended Use:

The KKT device is to be used in the aid of management of chronic pain due to non-congenital defects. The device can be used as part of a series of steps in the total care of the patient. The procedure involves the use of diagnostic imaging that qualifies the misalignment between vertebrae. The treatment is then administered using the KKT device to deliver precise impulses at a required vector configuration.

6. Technical Description:

The KKT Device's mode of action consists of low-intensity mechanical impulses applied to the treatment site in a controlled and repeatable manner. The control of the direction (vector), amplitude and duration of the impulses allows for a known, finite, and predetermined amount of force and/or energy to be applied to the treatment site. This control is predetermined and then prescribed by a qualified medical practitioner where the treatment parameters to be correlated with (or derived from) data from X-rays, imaging systems, and physiological length, strength or distance measurements and used for the patient's treatment.

The treatment protocol consists of a series of pulses applied to the atlas vertebra. Each pulse consists of a constant 16Hz frequency for approximately 750msec, a frequency sweep of 50 to 80 Hz in steps of 1 Hz for one full cycle each, followed by an extension while a twist is applied through the stepper motor, then a pause for approximately 750msec before the next pulse. The number of pulses can be set by the operator as can the amplitude of the stylus vertical motion and the amount and direction of the rotation.

The device consists of a treatment head supported by an electrically actuated stand. Power is supplied through a grounded receptacle to an auto sensing 24VDC power supply. All actuators and controls are powered at 24VDC or lower. The vertical tower is positioned manually by sliding on the base plate and vertical and horizontal adjustment is controlled by redundant momentary switches located on either side of the horizontal arm. The position of the treatment head is set manually using the positioning display on the LCD screen mounted on the horizontal arm. Treatment parameters for duration and intensity are entered using the same screen or automatically through Client Application software. A release mechanism is incorporated into the treatment stylus to prevent excessive

pressure being applied to the patient. This mechanism is interlocked through firmware to halt treatment and raise the treatment head when activated.

7. Comparison to Predicate

The (KKT-M2) has the same intended use and indications for use as the previously cleared device (KKT-M1), as well as similar performance and principles of operation. The technological differences between the (KKT-M2) and predicate KKT-M1 device is primarily improvement in design and manufacturing of the device. The device, its components, and its operation have been thoroughly tested for safety and effectiveness to ensure of safety and effectiveness of the device.

Manufacturer	**Optima Health Solutions**	**Optima Health Solutions**
Trade Name	**KKT-M1**	**KKT-M2**
510(k) Number	K060043	Pending
Product Code	LXM	LXM
Regulation Number	Unclassified	Unclassified
Regulation Name	Manipulator, plunger-like device	Same
Indications for Use	The KKT device is to be used in the aid of management of chronic pain due to non-congenital defects. The device can be used as part of a series of steps in the total care of the patient. The device is to be used for the treatment of vertebral motor units which appear to be fixated. The procedure can involve xray analysis that quantifies the lateral and rotational misalignments between the vertebrae. The treatment is then administered using the KKT device to deliver precise impulses at a required vector configuration.	The KKT-M2 device is to be used in the aid of management of chronic pain due to non-congenital defects. The device can be used as part of a series of steps in the total care of the patient. The procedure involves the use of diagnostic imaging that qualifies the misalignment between vertebrae. The treatment is then administered using the KKT –M2 device to deliver precise impulses at a required vector configuration.
Intended Use/ Operation of device	The KKT device is to be used in the aid of management of chronic pain due to non-congenital defects.	Same
Components (System)	Touchscreen Horizontal Arm Vertical Tower Base plate Transducer head Stylus	Same
Software	Contains firmware	Same
Mechanical		
Diameter	0.375 inches	15 mm
Stylus material	Carbon fiber	Acrylic
Stylus tip	Delrin	Elastosil R401/60
Linear motion		
Distance	0.125 inches max.	Same

Manufacturer	**Optima Health Solutions**	**Optima Health Solutions**
Trade Name	**KKT-M1**	**KKT-M2**
Motion	Sinusoidal	Same
Frequency	50 Hz to 100 Hz, 2 Hz increments (1 sweep =1 cycle)	50-80Hz
Force	6 lbs (2.7 kg) max	5lbs maximum
Cycles	User controlled	User controlled
Rotational motion		
Angle	+/- 30 deg max.	Same
Direction	Clockwise, counterclockwise	Same
Repetitions	Once per cycle	Same
Limits	Electronic and mechanical stops	Same
Positioning Base & Stand Adjustments		
Stylus tip		
Vertical motion	13 (+/-) inches Electrically powered	Up to 3mm (1/8") during treatment. Maximum travel from lowest to highest points of the vertical leadscrew is 26cm.
Horizontal transverse motion	10 inches Manual with friction lock Perpendicular to patient	Distance unit can travel along base plate rail along the transverse patient plane is at least 50cm in each direction from center point. Manual operation with adjustable friction brake.
Horizontal axial motion	10 inches Manual with friction lock Perpendicular to patient	Arm extends/retracts horizontally axially a total of 36cm. Motion is lead-screw driven, with braking mechanism incorporated into the lead screw controller.
Horizontal rotation	+/- 45 deg from normal, centered position, positive detent/lock at center	N/A
Transducer head/armature adjustments		
Horizontal motion	Horizontal motion	Same
Angular motion	Angular motion	Same
Interface Transducer head	Interface Transducer head	Same
Display	Display	LCD touchscreen display
Keypad	Keypad	Same
Communications	Communications	USB serial
Fuse (for 24 VDC transducer power)	3 AG 4A, 250V	1.6A 250VAC
KKT Device System		
Mains power supply	Mains power supply	Same
Fuse, mains	Fuse, mains	Same
Environment	15C to 40C 10% - 90% RH	Same
Storage	-20C to 50C 10% to 90% RH (non-condensing)	-5C to 35C 10% to 90% RH, non-condensing
Weight	150 lbs (66 kg)	350 lbs

Manufacturer	**Optima Health Solutions**	**Optima Health Solutions**
Trade Name	**KKT-M1**	**KKT-M2**
External switch rating	1 A @ 240 VAC/DC (resistive)	6A @ 250VAC
Accessories		
Standard	AC line cord Foot switch	AC line cord User Manual
Optional	Start/stop switch Motorized bed interface	Same

8. Standards and Testing

The device has been successfully tested to the following standards by accredited testing laboratories for performance and safety testing.

#	Standard	Standard Title	Version	Date	Cert./ Report #
1	IEC 60601-1.1-2	Medical electrical equipment – Part 1-2	Ed 3	Mar-30-2007	27382 Rev1.4
2	IEC 60601-1	Medical electrical equipment – Part 1	Ed 3	Dec-2005	CB Certification US/3467/ITS 100290268BOX-001
3	IEC 62366	Application of Usability Engineering to Medical Device	Ed 1	Oct-18-2007	100290268BOX-002

Additionally the KKT-M2 has been tested and approved for use sale and marketing into other markets including, Canada, CE, and China.

9. Conclusion

This submission for the second generation of Khan Kinetic Treatment device (KKT-M2) seeks to obtain approval for marketing in the US, a product that is intended to be used in medical clinics, more specifically, orthopedic clinics. The device's intended use is for aid in management of chronic pain. More specifically, conditions of chronic pain arising from structural anomalies such as misalignments and imbalances of the soft tissues of the back and neck. The KKT-M2 has been tested for safety and effectiveness with improved features in comparison to the previously cleared device KKT-M1, and its predicates.

In comparison to handheld devices or manual manipulation that deliver a single, relatively uncontrolled blow to the affected area, KKT-M2 delivers a highly controlled, low force, repetitive impulse to the treatment location, resulting in a controlled vibration, as is disclosed in the technical reports. This can be felt by the practitioner as impulse waves extending from the treatment location. As a result, KKT gently urges realignment of the skeletal system over one or more treatments.

Standardized operating conditions:

- Force is accurately adjustable and not more than 5 pounds, with suggested force of 10.3 N (2.3 pounds);
- Stylus vertical displacement of up to 3mm (1/8") during treatment
- Wave form is sinusoidal; and
- Frequency is accurately adjustable and not more than 110 Hz, with suggested treatment being 16Hz + 50-80Hz for disc treatment.

The results from the studies cited above support the efficacy of the treatment. Further, there have been no adverse outcomes reported in over 10,000 KKT treatments.

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

January 23, 2014

Optima Health Solutions International
c/o Diane Sudduth, MS, MPH
Emergo Group
816 Congress Avenue, Suite 1400
Austin, TX 78701

Re: K130666
Trade/Device Name: Khan Kinetic Treatment Device (KKT-M2)
Regulatory Class: Unclassified
Product Code: LXM
Dated: November 1, 2013
Received: November 4, 2013

Dear Ms. Sudduth:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130666

Device Name: Khan Kinetic Treatment Device (KKT-M2)

Indications For Use:

The KKT-M2 device is to be used in the aid of management of chronic pain due to non-congenital defects. The device can be used as part of a series of steps in the total care of the patient. The procedure involves the use of diagnostic imaging that qualifies the misalignment between vertebrae. The treatment is then administered using the KKT-M2 device to deliver precise impulses at a required vector configuration.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Carlos L. Pena -S