510(k) SUMMARY

Khan Kinetic Treatment Device (KKT-M1)

Common Name: Manipulator Device
Classification: Unclassified

Optima Health Solutions International, Inc.
Unit 303, 828 West 8th Avenue
Vancouver, British Colombia, Canada
V5Z 1E2

Contact: Bram Ramjiawan Tel: 204-984-4623 Fax: 204-983-8835
Prepared: November 6, 2005

A. LEGALLY MARKETED PREDICATE DEVICES

The Khan Kinetic Treatment Device (KKT-M1) is equivalent to a similar pressure applying device - The Atlas Orthogonal Percussion Instrument.

Information on the Predicate Device

Name:	The Atlas Orthogonal Percussion Instrument
Classification Product Code:	LXM
510(k) Number:	K951217
Marketed by:	Sweat Chiropractic Clinic
Address:	3274 Buckeye Rd. N.E, Atlanta, GA 30341
FDA Establishment #:	1039671

Summary: The device is a pressure applying device that is a comparable to the KKT-M1 device.

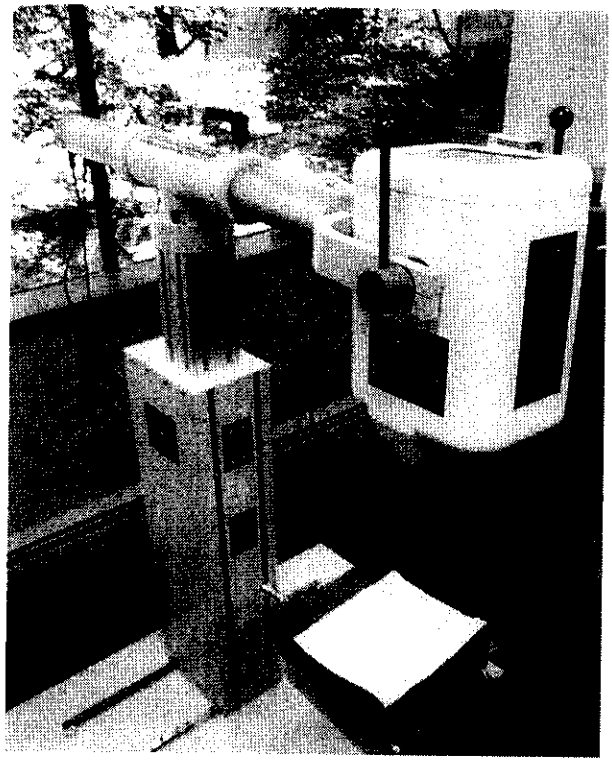
B. DEVICE DESCRIPTION

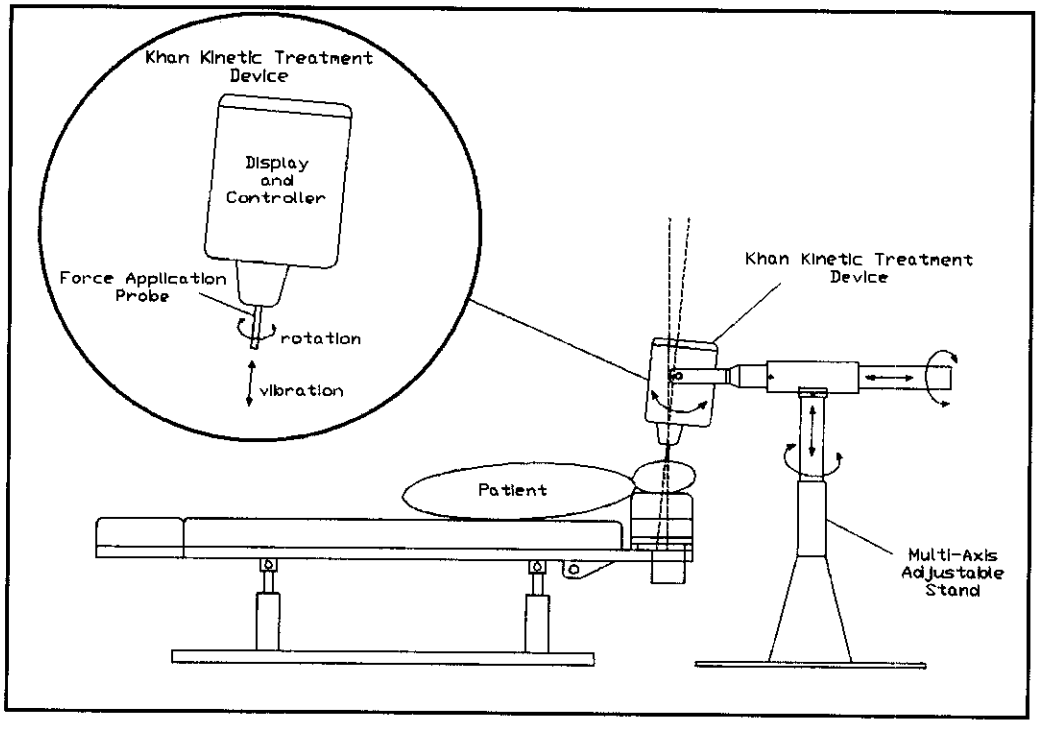
Indication for use

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 x-ray 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 Device

The KKT device provides an integrated treatment system unlike manual manipulation of the upper cervical spine, applying significantly smaller forces than those applied manually. While other handheld devices have been used which employ similar treatment methods, the KKT device provides significant advancement and improvement in positioning application and repeatability.





Similarities and Differences to Comparative Device

The KKT device is similar and comparable to pressure applying devices (reference CFR 21 Part 890, Sec. 890.5765) as well as percussion devices/percussors (reference CFR 21 Part 882, Sec. 882.1700). A comparable pressure applying device is the Atlas Orthogonal Percussion Instrument which is from Sweat Chiropractic Clinic. The Atlas Orthogonal Percussion Instrument is registered with the FDA under establishment license number 1039671 and is patented under US Patent No. 4,461,286 (issued to Sweat). Other devices patented that are similar or operate using the same principles include: US Patent No. 4,841,955 (issued to Evans), US Patent No. 4,549,535 (issued to Wing), US Patent No. 5,618,315 (issued to Elliott), and US Patent No. 6,602,211 (issued to Tucker).

The key difference between the KKT device and applying pressure via manual manipulation or via different impulse methods is that the KKT device provides an integrated treatment system that applies adjustable, modifiable forces in a more effective method and it provides significant advancement and improvement in positioning, accuracy and repeatability.

C. TESTING

Requirement	Method of Compliance	Comment
Electrical	CSA 601.1 and UL 2601/60601-1, with CB Report done to IEC 60601.1	See the KKT Device Technical File
EMC	IEC 60601.1-2	See the KKT Device Technical File
KKT Device Verification Test Plan	Formal Design Verification Procedure	See the KKT Device Technical File

D. STANDARDS

The KKT device was designed according to the medical device standards IEC60601-1, IEC60601-1-2 and the relevant EMC standards:

- EN55022
- EN61000

These standards, or variations thereof, are relevant to entry into other markets such as China, Canada, Australia and Japan.

The KKT device has received Health Canada approval for use, sale and marketing.

E. CONCLUSIONS

This submission for the Khan Kinetic Treatment device seeks to obtain approval for marketing in the US, a product that is intended to be used in chiropractic 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 muscle imbalances. The device is safe and effective and is similar to the FDA approved predicate device (The Atlas Orthogonal Percussion Instrument (K951217)).

The current practices of performing manual spinal adjustments for the relief of pain have received negative attention due to the occurrence of injury. Unintended injury in these situations has occurred because of unregulated manual force generated by the individual clinician.

This device was developed to minimize (relative to the current practice of manual adjustments) potential harm by having a system that generates impulses as opposed to uncontrolled mechanical force alone to stimulate areas of interest.

Numerous built-in mechanisms have been incorporated into the device to ensure safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2006

Optima Health Solutions International, Inc.
c/o Dr. Bram Ramjiawan
Industrial Technology Advisor
IRAP West
National Research Council
Industrial Research Assistance Program
435 Ellice Avenue
Winnipeg, Manitoba, Canada
R3B 1Y6

Re: K060043
Trade/Device Name: Khan Kinetic Treatment Device (KKT-M1)
Regulatory Class: Unclassified
Product Code: LXM
Dated: November 27, 2005
Received: January 26, 2006

Dear Dr. Ramjiawan:

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.

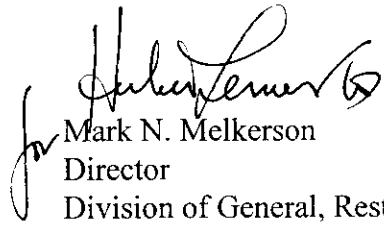
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060043

Indications for Use

510(k) Number (if known):
K060043

Device Name:
Khan Kinetic Treatment (KKT) Device

Indications for Use:
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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 CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060043