510(k) Summary **K080261**

Device Name: Impulse iQ Adjusting Instrument

APR 11 2008

Manufacturer: Neuromechanical Innovations, LLC
11011 S. 48th St., Suite 205
Phoenix, AZ 85044

Contact: Christopher J. Colloca, D.C.
Phone: 480-785-8442
Fax: 480-785-3916
Email: DrC100@aol.com

Trade Name(s): Impulse iQ Adjusting Instrument or Impulse iQ

Common or Usual Name: Chiropractic Adjusting Instrument

Product Code: LXM

Classification Name: Manipulator, Plunger-like Joint

Classification: Unclassified

Predicate Devices for Substantial Equivalence:

K023462	Impulse Adjusting Instrument
K930431	Arthrostim Manipulator
K973914	FRAS, Sense Technology, Inc.
K003185	Full Spectrum Activator III
K010851	Harrison Hand Held Adjusting Instrument

Panel: Physical Medicine

Performance Standards: None known established

Performance Data: The Impulse iQ Adjusting Instrument has been mechanically tested and found to produce approximately 100 N, 200 N, and 400 N on its low, medium, and high force settings respectively. Total peak force output is also dependent upon operator preload. The pulse rate varies between 4-12 Hz.

Device Description & Specifications: The Impulse iQ Adjusting Instrument is a hand-held electromechanical chiropractic adjusting instrument. The device has three force settings (low, medium, high), a preload-control indicator light that turns from red to green upon achieving the proper preload, and an internal accelerometer to provide closed-loop feedback controlling thrust pulse rate. The device is only intended for use from a health care professional licensed by the law of the state that he or she practices.

Intended Use: The Impulse iQ Adjusting Instrument is intended for chiropractic adjustment, mobilization, or manipulation of the musculoskeletal joints of the spine and/or extremities, or for soft-tissue musculoskeletal mobilization by a licensed health care professional only. For external use only.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Neuromechanical Innovations, LLC
% Christopher J. Colloca, D.C.
11011 S. 48th Street, Suite 205
Phoenix, Arizona 85044

Re: K080261
Trade/Device Name: Impulse iQ Adjusting Instrument
Regulatory Class: Unclassified
Product Code: LXM
Dated: March 20, 2008
Received: March 25, 2008

Dear Dr. Colloca:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240)- 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240)- 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or 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

Indications for Use Statement

510(k) Number: K080261

Impulse iQ Adjusting Instrument Intended Use:
The Impulse iQ Adjusting Instrument is intended for chiropractic adjustment, mobilization, or manipulation of the musculoskeletal joints of the spine and/or extremities, or for soft-tissue musculoskeletal mobilization by a licensed health care professional only. For external use only.

Prescription Use ___X___ (Part 21 CFR801 Subpart D)

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm

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

510(k) Number K080261