6. 510(k) Summary of Safety and Effectiveness

OCT 2 3 2007

This 510(k) Summary of Safety and Effectiveness for the Activator V is submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(k) Summary.

Applicant:	Activator Methods International Ltd.
Address:	2950 N. Seventh Street, Suite 200
	Phoenix, AZ 85014 USA
Contact Person:	Arlan W. Fuhr, D.C.
Telephone:	602-224-0220
Fax:	602-224-0230
Preparation Date:	September 4, 2007
Device Trade Name:	Activator V
Common Name:	Chiropractic adjusting instrument
Classification Name:	Plunger-like joint manipulator
Product Code:	LXM
Legally Marketed Predicates:	K003185, Full Spectrum Activator III K010851, Harrison Hand Held Adjusting Instrument K023462, Impulse Adjusting Instrument
Device Description:	The Activator V is a hand-held electromechanical chiropractic adjusting instrument with a plunger-like mechanism that is intended to be used for chiropractic adjustment of the spine and extremities. The device is only intended to be used by a health care professional licensed by the state in which he or she practices. The thrust is provided by battery power rather than manual force. This makes it easier and less tiring for the chiropractor.

510(k) Summary of Safety and Effectiveness for the Activator V, continued:

Intended Use:	The Activator V is indicated for chiropractic adjustment of the spine and extremities. It is intended for external use only
Performance Data:	The Activator V has been mechanically tested and shown to deliver approximately 75,125, 175 or 250 N, depending on the selected thrust setting. The rechargeable battery has been tested for safety and performance by the battery manufacturer.
Conclusion:	The Activator V is substantially equivalent to the predicate plunger-like chiropractic adjustment devices with respect to intended use, performance, and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2007

Activator Methods International, Ltd.
% Arlan W.Fuhr, D.C.
President
2950 North 7th Street, Suite 200
Phoenix, Arizona 85014

Re: K072519
Trade/Device Name: Activator V Spinal Adjusting Instrument
Regulatory Class: Unclassified
Product Code: LXM
Dated: September 4, 2007
Received: September 7, 2007

Dear Dr. Fuhr:

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 its toll-free number (800) 638-2041 or (240) 276-3150 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

5. Indications for Use Statement

Activator V Spinal Adjusting Instrument Intended Use:

The Activator V is indicated for chiropractic adjustment of the spine and extremities. It is intended for external use only.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K072519