Activator Methods, INC.
DR. ARLAN W. FUHR, PRESIDENT AND CO-FOUNDER

JAN 27 1998

K973506

**510(k) Summary- Activator II®**

September 11, 1997

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|---|---|---|
| Manufacturer: | Activator Methods, Inc.<br>3714 E. Indian School Road<br>Phoenix, Arizona 85060-0317 | |
| Contact: | Arlan W. Fuhr, D.C.<br>phone: (602) 224-0220<br>fax: (602) 224-0230 | |
| Trade name: | Activator II® | |
| Common name: | chiropractic adjusting device | |
| Classification name: | Plunger-like joint manipulator | |
| Substantially equivalent to: | Activator® | *preamendments device*<br>Activator Methods<br>Phoenix, Arizona |
| | Integrator | *K950646*<br>HRI, Inc. |
| | Arthrostim | *K930431*<br>Freeman Procedure Seminars |

Device Description:

The Activator II ® is a chiropractic adjusting instrument for use in spinal manipulative therapy. The instrument is approximately seven (7) inches in length and approximately 2.5 inches wide at the handles. The major components of the device include handles for holding the device and applying thrust, a thrust element for delivering an input force to the patient, a body contact member, a spring for propelling the thrust element, and an adjustment knob. The body contact member is manufactured from silicone rubber. The adjustment knob is used for manually adjusting the amount of potential energy imposed on the spring and for controlling the magnitude of the resulting input force. When the handle is depressed, the body contact member applies the force in a specific line of drive at a rapid speed. This action is similar to a practitioner manually applying thumb thrust at specific contact points to achieve chiropractic adjustment.

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Intended Use: chiropractic adjustment of the spine and extremities.

Comparison to predicate device:

| | | |
|---|---|---|
| Indicated for chiropractic adjustment of the spine? | yes | yes |
| Hand held adjusting device? | yes | yes |
| Impact force derived by spring energy? | yes | yes |
| Adjustable impact force? | yes | yes |
| Silicone rubber body contact member? | yes | yes |
| Weighted anvil tip? | no | yes |

Table 1. Substantial Equivalence Comparison

Summary of data upon which substantial equivalence was based:

As a result of the research on the Activator I® which included a 46 gram weighted anvil tip, the formation of the Activator II® evolved. This Activator II® was tested on a human subject and an animal subject. Performance data for the Activator II® has been published in the Journal of Manipulative and Physiological Therapeutics, Volume 9, Number 1, March 1986. In this study, entitled "Accuracy of Piezoelectric Accelerometers Measuring Displacement of a Spinal Adjusting Instrument," an electronic system to measure the displacement of the Activator II® instrument was examined. Results demonstrate the effectiveness of the instruments to cause vertebral movement for chiropractic adjustment at very low energy.

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Fax number: (602) 224-0230

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 1998

Arlan W. Fuhr, D.C.
President
Activator Methods, Inc.
3714 East Indian School Road
Phoenix, Arizona 85018

Re: K973506
Activator II®
Regulatory Class: Unclassified
Product Code: LXM
Dated: December 4, 1997
Received: December 16, 1997

Dear Dr. Fuhr:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number:** K973506

**Device Name:** Activator II®

**Indications for Use:** The Activator II® is indicated for chiropractic adjustment of the spine and extremities.

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

Concurrence of CRDH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973506

Prescription Use X OR Over-the Counter Use _____

(Per 21 CFR 801.109)