OCT 0 9 2002

510(k) Summary
Frye Adjusting Instrument

Manufacturer: Frye Health Systems Inc
3126 S. Garnett Road, Suite H
Tulsa, OK 74146

Contact: Bruce Frye, D.C.
918-665-0036

Trade name: Frye Adjusting Instrument

Common name: chiropractic adjusting device

Classification name: Plunger-like joint manipulator

Substantial equivalence: FS Activator® III, K003185
Activator Methods, Phoenix, Arizona

Intended Use:

The Frye Adjusting Instrument is intended for chiropractic adjustment of the spine and extremities.

Device Description:

The Frye Adjusting Instrument is a chiropractic, adjusting instrument for use in spinal manipulative therapy. The Frye Adjusting Instrument is a modification of the Full Spectrum Activator® III Adjusting Instrument developed to offer easier use to those chiropractors that have limited strength or dexterity in their hands. Typically, these are chiropractors that have arthritis, age-related problems, or have a physical disability of their upper extremity. Thus, these chiropractors have difficulties using currently available adjusting instruments. The main differences between currently available adjusting instruments, such as the FS Activator® III, and the Frye adjusting instrument are that the Frye adjusting instrument is activated pneumatically by a simple push-button and it is shaped in a 'gun-like' configuration rather than a 'plunger-like' configuration.

Comparison to predicate device:

Like the FS Activator® III, the Frye Adjusting Instrument is a manual hand-held chiropractic adjusting device which provides a repeatable force and displacement to the spine and extremities when activated. Both devices have a precision force setting feature and a silicone rubber body contact member. See Table 1 below for a comparison of the Frye Adjusting Instrument and the FS Activator® III.

Table 1. Substantial Equivalence Comparison

	FS Activator® III	**Frye Adjusting Instrument**
Indicated for chiropractic adjustment of the spine?	Yes	Yes
Hand held adjusting device?	Yes	Yes
Impact force delivered by spring energy?	Yes	Yes
Adjustable impact force?	Yes	Yes
Silicone rubber body contact member?	Yes	Yes
Precision operating force setting?	Yes	Yes
Spring activated directly by chiropractor?	Yes	No, is activated pneumatically

Summary of data upon which substantial equivalence was based:

Bench data performed by an independent laboratory compared the Frye Adjusting Instrument to the FS Activator® III. Results indicated that both devices produce similar peak dynamic loads at minimum, mid, and maximum settings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 9 2002

Frye Health Systems
c/o Ms. Deborah F. Koeneman
Regulatory Consultant
2751 East Hale Street
Mesa, Arizona 85213

Re: K021238
Trade/Device Name: Frye Adjusting Instrument
Regulation Number: n/a
Regulation Name: n/a
Regulatory Class: unclassified
Product Code: LXM
Dated: August 14, 2002
Received: August 15, 2002

Dear Ms. Koeneman;

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

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

Indications for Use Enclosure

510(k) Number: K021238

Device Name: Frye Adjusting Instrument

Indications for Use: The Frye Adjusting Instrument 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)

Prescription Use X OR Over-the Counter Use _____

(Per 21 CFR 801.109)

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

510(k) Number K021238