2/12/99

K982142

MXM 2/11/99

**510(k) Summary**

**Hand Biomechanics Lab, Inc.**
**77 Scripps Drive, Suite 104**
**Sacramento, CA 95825-6209**

**Contact: Timothy R. Stallings**
**Phone: (916) 923-5073**
**Fax: (916) 920-2215**
**Email: trstallings@handbiolab.com**

**Name of Device:**

| | |
|---|---|
| *Regulatory Classification:* | Class II |
| *Classification Name:* | Component, Traction, Invasive [888.3040] |
| *Common Name:* | External Fixator System |
| *Trade Name/Proprietary Name:* | Agee-WristJack Fracture Reduction System (sterile version), Item No. CFD-147 |
| *Performance Standards:* | No performance standards exist for this device. |

**Predicate Device:**

Agee-WristJack Fracture Reduction System (non-sterile version), Item No. CFD-47, K842493

**Description of Device:**

The Agee-WristJack System is an external fixation system used for reduction and fixation of distal radius fractures. The system includes an adjustable reduction/fixation frame (fixator), application instrumentation and skeletal fixation pins.

The fixator element has multiple adjustments to aid in fracture reduction and stabilization of distal radius fractures. The device and instrumentation are constructed of polyetherimide resin, stainless steel and aluminum alloy. The fixation pins are constructed of implant grade 316 stainless steel per ASTM F138.

**Intended Use:**

Fracture reduction and external fixation for treatment of distal radius fractures.

**Technological Characteristics Compared to Predicate Device:**

All the device components and materials of the Agee-WristJack Fracture Reduction System (sterile version) are identical to the device components and materials of the predicate device, except this device is delivered sterile. The predicate device requires customer sterilization prior to use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 1999

Mr. Timothy R. Stallings
Manufacturing Manager
Hand Biomechanics Lab, Inc.
77 Scripps Drive, Suite 104
Sacramento, California 95825

Re: K984442
Agee-WristJack Fracture Reduction System
(sterile version), Item No. CFD-147
Regulatory Class: II
Product Code: JEC
Dated: December 11, 1998
Received: December 14, 1998

Dear Mr. Stallings:

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 (if known):_____

Device Name: Agee-WristJack Fracture Reduction System (sterile versions)

Indications For Use:

Fracture reduction and external fixation for treatment of distal radius fractures.

(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 Devices
510(k) Number K984442

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)