K992970

NOV - 8 1999

HAND BIOMECHANICS LAB, INC.

510(k) Summary

Contact Information: Hand Biomechanics Lab, Inc.
77 Scripps Drive, Suite 104
Sacramento, CA 95825
Telephone: 1(916) 920-0484
Facsimile: 1(916) 920-2215
Contact Person: Jeff Woodhouse

Trade Name: Digit Widget

Common Name: PIP Joint External Fixation Device

Classification Name: Pin, Fixation, Threaded

Device Product Code: 87JDW

Regulation Number: 888.3040

Substantial Equivalence: The Hand Biomechanics Lab, Inc. Digit Widget is substantially equivalent in material, function, performance, and design to the Proximal Interphalangeal (PIP) Joint External Fixation device (Compass® Proximal Interphalangeal Joint Hinge) marketed by Smith Nephew Richards. The products have comparable indications for use.

Device Description: The Digit Widget is an external fixation system designed to effect rotation of an injured or diseased finger, to help regain, maintain, or increase the range of motion of the proximal interphalangeal (PIP) joint. It utilizes standard small diameter bone pin (Kirschner wire) fixation techniques and procedures for placement. The device acts about the axis of rotation of the PIP joint and allows some adjustability to permit fine tuning of device alignment relative to the joint's axis. During treatment, the surgeon or hand therapist (under order from the physician) may be required to periodically adjust the torque provided by the traction mechanism, by changing or adding orthodontic elastics. The orthodontic elastic can be removed temporarily to permit active range of motion exercise. The Digit Widget traction device is made from plastic and metal materials. Fixation pins (Kirschner wires) are made from implant grade stainless steel. An included wrist splint is made of neoprene and nylon, with Velcro attachment provisions. All components are designed for single use only.

Indications For Use: The Hand Biomechanics Lab, Inc. Digit Widget is intended for use in treating PIP joint flexion contractures with an associated loss of range of motion

Predicate Devices: The Proximal Interphalangeal (PIP) Joint External Fixation devices marketed by BIOMET, Inc. (K980370) and Smith Nephew Richards (K970713) represent predicate devices relative to the Hand Biomechanics Lab, Inc. Digit Widget .

Clinical Tests: None

Adverse S&E Information: None

John M. Agee

John M. Agee, M.D.
President & C.E.O.

9-1-99

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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John M. Agee, M.D.
President and CEO
Hand Biomechanics Lab, Inc.
77 Scripps Drive, Suite 104
Sacramento, California 95825

Re: K992970
Trade Name: Digit Widget
Regulatory Class: II
Product Code: JDW
Dated: September 1, 1999
Received: September 3, 1999

Dear Dr. Agee:

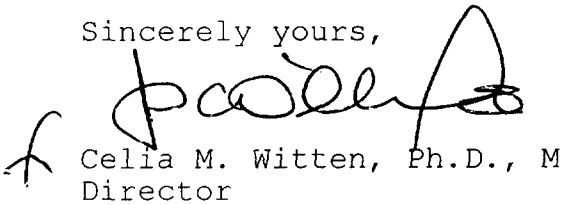
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



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): K992970

Device Name: Digit Widget

Indications For Use:

The Hand Biomechanics Lab, Inc. Digit Widget is intended for the following indication:

1. PIP joint flexion contractures with an associated loss of range of motion.

(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 K992970

Prescription Use Y OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)