

January, 2009

To Whom it Concerns:

RE: FDA 510(k) approval letter

The attached FDA 510(k) approval letter dated Jan. 9, 2008 is for the
Trade/Device Name:

F3 Fractured Finger Fixator (catalog number FCS-400).

This is the same product as the TurnKey FCS (catalog number FCS-400).

We were forced to change the name of the product by a competitor that felt the name "F3" and the name of one of their products was too similar. The name was changed to TurnKey FCS in June, 2008. There were no changes to the product itself or its' indications for use.



JAN - 9 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Hand Biomechanics Lab., Inc.
% Mr. Jeff Woodhouse
77 Scripps Drive
Suite 104
Sacramento, CA 95825-6209

Re: K072432

Trade/Device Name: F3 Fractured Finger Fixator
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JEC
Dated: January 2, 2008
Received: January 3, 2008

Dear Mr. Woodhouse:

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.

Page 2 – Mr. Jeff Woodhouse

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

Indications for Use

510(k) Number (if known): K072432

Device Name: F3 Fractured Finger Fixator

Indications for Use:

The F3 Fractured Finger Fixator is indicated for the treatment of acute, unstable dorsal fracture-dislocations of the proximal interphalangeal (PIP) joint of the fingers in which external skeletal fixation as provided by the F3 Fractured Finger Fixator alone is sufficient to obtain and maintain concentric reduction of the fracture-dislocation during bone and soft tissue healing.

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 IF NEEDED)

Barbara Mueller-Johnson

(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of General, Restorative,
and Neurological Devices

510(k) Number K072432