October 22, 2018

Hand Biomechanics Lab, Inc.
Dustin Dequine
Operations Manager
77 Scripps Drive, Suite 104
Sacramento, California 95825

Re: K181192
Trade/Device Name: PIP Fix
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: JEC
Dated: October 17, 2018
Received: October 19, 2018

Dear Dustin Dequine:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Peter G. Allen -S
2018.10.22 09:49:51 -04'00'

FOR Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181192

Device Name

PIP Fix

Indications for Use *(Describe)*
The PIP Fix is indicated for the treatment of unstable dorsal fracture dislocations of the proximal interphalangeal (PIP) joint of the fingers in which external skeletal fixation as provided by the PIP Fix alone is sufficient to obtain and maintain concentric reduction of the fracture dislocation during bone and soft tissue healing.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Hand Biomechanics Lab

510(k) Summary

I. Submitter

Hand Biomechanics Lab, Inc.
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Contact Person: Dustin Dequine
Email: ddequine@handbiolab.com

Date Prepared: October 17, 2018

II. Device

Trade Name: PIP Fix
Model Number: PFX-426
Common Name: External Fixator System
Classification Name: Component, Traction, Invasive [21CFR 888.3040, Product Code JEC]

III. Predicate Device

F3 Fractured Finger Fixator (Turnkey FCS), K072432
This predicate has not been subject to a design related recall.

IV. Device Description

The PIP Fix is an external skeletal fixator designed to obtain and maintain concentric reduction of an unstable dorsal fracture dislocation of the proximal interphalangeal (PIP) joint. This device is capable of exerting both palmar translation and distal length restoration forces on the middle phalanx while simultaneously lifting the distal end of the proximal phalanx to restore joint alignment. With the dorsal dislocation of the middle phalanx reduced, the fractured fragments of the joint surface are reopposed. The effect of the PIP Fix is present throughout the complete range of finger motion allowing full active flexion and extension during healing of the bone and soft tissues.

The PIP Fix is installed by a surgeon in a healthcare facility / hospital environment. Included with the gamma irradiated, sterile PIP Fix is a Pin Placement Guide that allows for a Transverse Bone Pin to be accurately placed through the axis of PIP joint rotation. A Dorsal Bone Pin is inserted vertically into the middle phalanx. The device is installed on the Dorsal Bone Pin and is linked to the Transverse Bone Pin with Elastic Bands. These bands provide the translating forces that hold the joint concentrically reduced. The device enables the surgeon to determine the distribution of the direction of the forces between palmar translation and distal length restoration. This is accomplished by rotating the Elastic Band posts about an arc concentric with the PIP joint axis such that the force vector resolution may be purely in a palmar translation direction or a combination of palmar translation and length restoration. An Angle Lock Screw locks the device in the chosen position to maintain the force distribution. A Tension Adjust Screw on the PIP Fix allows the surgeon to adjust the amount of tension in the Elastic Bands so they exert the least amount of tension necessary to maintain joint alignment.

The PIP Fix is manufactured using metal and Ultem plastic. The Bone Pins are fabricated from 316L stainless steel per ASTM F138. Both latex and non-latex elastic bands are supplied with the device. All components are designed for single use only. The device is typically worn for 6 to 8 weeks depending on the rate of healing and the surgeon's assessment of the same. During this time, the Bone Pins are the only portion of the device contacting or penetrating the skin in a non-transient manner.

For reference, below is an illustration of the sterile components provided with the PIP Fix. The sterile Elastic Bands are omitted for clarity from the illustration.

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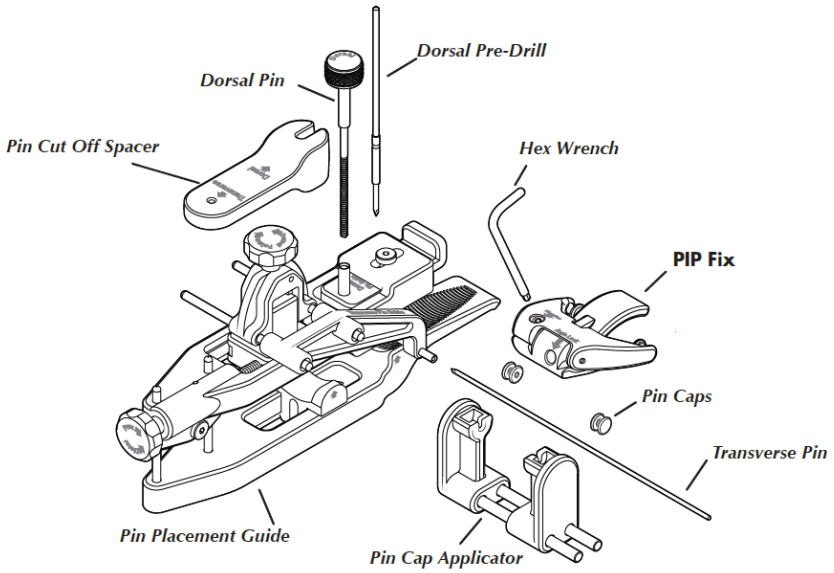

V. Indications for Use

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

The Indications for Use statement for the PIP Fix device is not identical to the predicate device; however, the differences do not alter the intended surgical use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use to treat unstable dorsal fracture dislocations of the PIP joint by applying forces directly to the proximal and middle phalanges to restore joint alignment. The predicate device Indication for Use is limited to "acute" unstable fracture dislocations of the PIP joint. This limitation resulted because the predicate device provided an insufficient length restoration force to consistently be effective for "chronic" dorsal fracture dislocations. That limitation was removed from the subject device Indication for Use because of its ability to provide a greater length restoration force sufficient to allow its use for "chronic" dorsal fracture dislocations. This was the design intent of the PIP Fix based on surgeon feedback and other inputs because certain patients require greater length restoration force to obtain and maintain both PIP joint and fracture reduction.

VI. Comparison of Technological Characteristics with the Predicate Device:

The PIP Fix is comparable to the predicate device with respect to function and application technique. Both are indicated for unstable dorsal fracture dislocations of the PIP joint and are attached to the finger using bone pins. Both use elastic bands to apply reduction forces across the PIP joint. The PIP Fix is capable of applying a greater length restoration force. The PIP Fix and predicate device are both made of the same plastic and metal components. Both are delivered to the customer sterile.

For comparison, the sterile components provided in the subject and predicate device are illustrated below (subject left, predicate right). The Pin Placement guide, Pin Cut Off Spacer, Dorsal Pre-Drill, Hex Wrench, Pin Caps, Transverse Pin, Pin Cap Applicator and Elastic Bands (not shown) are identical between both products. The threads of the Dorsal Pin of the subject device extend further up the pin.

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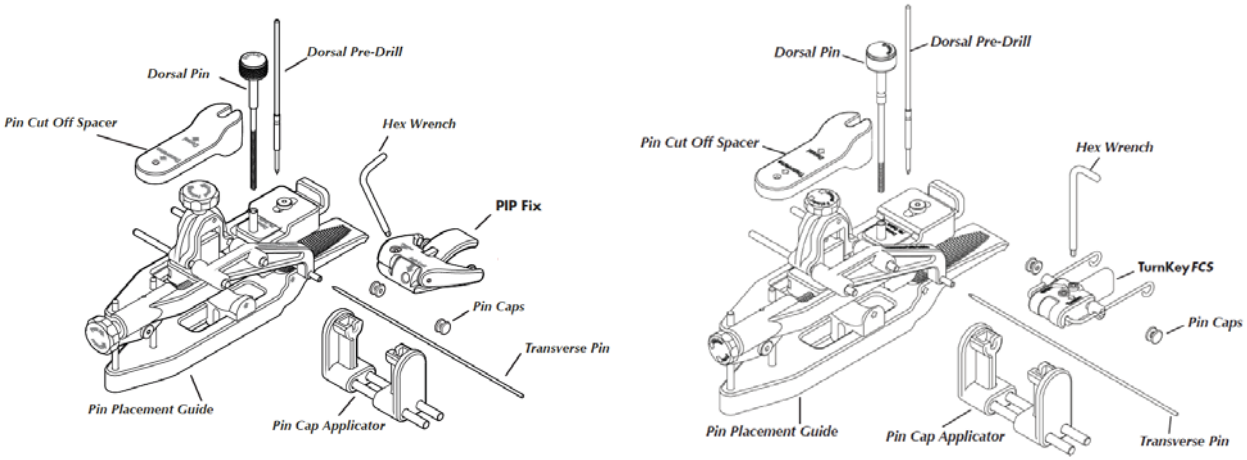
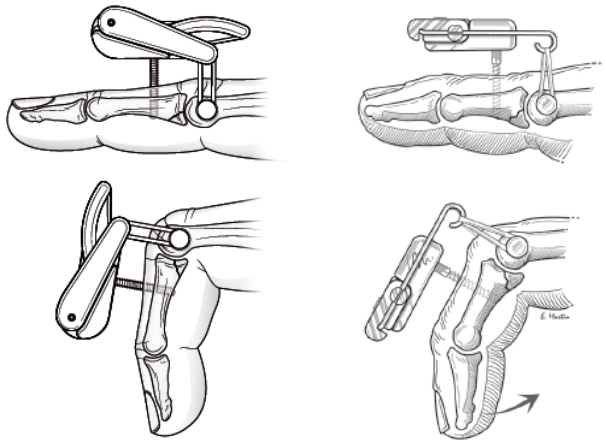
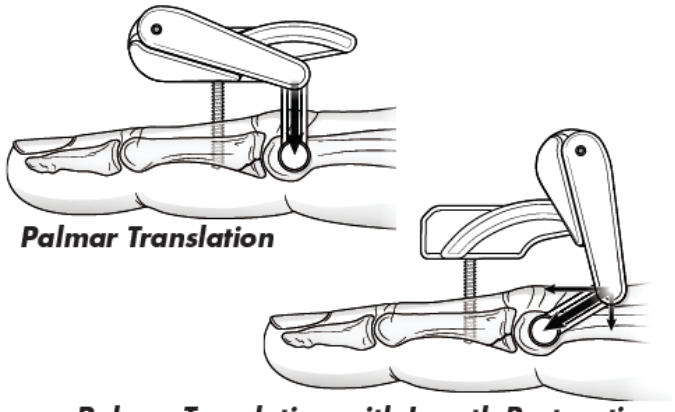


The primary technological difference lies in the device itself. The illustrations below show the device installed on the finger with the subject on the left and predicate on the right. For simplicity, both devices are shown configured for palmar translation without length restoration forces.



In the above configuration, the subject and predicate devices function identically. The subject device has the added capability of repositioning the elastic band posts to alter the direction of force. This force vector may be resolved into a palmar translation force and length restoration force as illustrated below. In the palmar translation illustration, the force vector arrow points down indicating the force applied to the middle phalanx translates it palmarly relative to the proximal phalanx. In the palmar translation with length restoration illustration, the force vector is resolved into two orthogonal directions.



Palmar Translation

Palmar Translation with Length Restoration

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VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Computational Analyses

Both the predicate and subject devices utilize forces produced by elastic bands to obtain and maintain PIP joint and fracture reduction. Computational analysis of the force performance of the PIP Fix is comparable to the predicate device when the devices are placed in the palmar translation only positions. The PIP Fix applies more length restoration force (5 times greater) than the predicate device when the devices are placed in the "translation & length restoration force" positions.

The dorsal pin for the PIP Fix is the same as the one used for the predicate device with the exception the threads extend further up the shaft. However, the overall length, minor and major diameters, and pitch are identical. Therefore, the only potential new failure mode related to the pin involves the side loading resulting from the length restoration force being greater for the PIP Fix. A computational analysis of the nominal bending stress on the dorsal pin as a result of the increased length restoration force indicated a 5x increase in bending stress for the PIP Fix. However, this increased stress still remains significantly below the pin material yield strength.

Bacterial Endotoxin Testing

A Bacterial Endotoxins Test (BET) was performed on the implantable components of the subject device. The results indicated that the detected endotoxin levels were less than the FDA guidance recommended endotoxin limit of 20.0 EU/device.

VIII. Conclusions

The predicate and subject devices operate under similar technological and functional principles using similar materials. Additionally, the predicate device has been legally marketed and sold for many years and historical feedback trended. It is in part due to this feedback, in fact, that the subject device was developed to address an unmet need from the surgical community of users. The proven history of the predicate device and similarity to the subject device demonstrate that the PIP Fix should perform as intended in the specified use conditions safely and effectively for the same intended use.