K041081

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Summary of Safety and Effectiveness for the Fragment Plate System

submitted by
Hand Innovations, Inc.
8905 SW 87 Avenue
Miami, FL 33176-2227
Phone: 1 (800)-800-8188

JUL 01 2004

Contact Person:	Al Weisenborn
Device Trade Name:	Fragment Plate System
Common Names:	Fragment Plates Screws, pins, and k-wires
Classification Names:	Plate, Fixation, Bone per 21 CFR § 888.3030 Smooth or threaded metallic bone fixation fastener per 21 CFR § 888.3040

Identification of a Legally Marketed Predicate Device

The Hand Innovations, Inc. Fragment Plate System is substantially equivalent to Distal Volar Fracture Repair System that is legally marketed and distributed by Hand Innovations, Inc.

Device Description

The Fragment Plate System is comprised of a variety of titanium plates with shapes and sizes designed for internal fixation of small bone fragments. The set also includes screws, pins, and k-wires. The screws and pins are have a center drive head and are 2.5 mm in diameter. The plates will include "Y," straight, right, and left configurations. Manual surgical instruments are supplied with the system to facilitate implantation.

Intended Use

The Fragment Plate System is intended for essentially non load-bearing stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, foot, wrist, ankle, humerus, scapula, finger, toe, pelvis, and craniomaxillofacial skeleton.

Summary of Technological Characteristics

A 13-point comparison of technological characteristics of the Hand Innovations, Inc. Fragment Plate System and the predicate device was performed. The devices were found to be substantially equivalent.

Summary of Performance Data

The Hand Innovations, Inc. Fragment Plate Systems comply with the following standards, practices, and guidances:

- ASTM F366 – 82 (Reapproved 2000), Standard Specification for Fixation Pins and Wires
- ASTM F 136 – 96, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (R56401) for Surgical Implant Applications.

The Hand Innovations, Inc. Fragment Plate System is substantially equivalent to Distal Volar Fracture Repair System that is legally marketed and distributed by Hand Innovations, Inc. This has been demonstrated through a 13-point technological comparison of features and bench testing.

The implantable and tissue contact materials used to fabricate the Fragment Plate System and Instruments have a long history of safe usage in medical devices. Since the Hand Innovations, Inc. Fragment Plate Systems meet the requirements of the stated standards and embody technological characteristics essentially identical to the predicate device, we believe the device is safe and effective and performs as well as or better than the predicate device. The Fragment Plate System will be manufactured per specifications using good manufacturing practices that ensure the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 01 2004

Al Weisenborn
Hand Innovations, Inc.
8905 SW 87 Avenue
Miami, Florida 33176-2227

Re: K041081
Trade/Device Name: Fragment Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: April 23, 2004
Received: April 27, 2007

Dear Weisenborn:

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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

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

Enclosure

Indications for Use

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510(k) Number (if known): K041081

Device Name: Fragment Plate System

Indications for Use:

The Fragment Plate System is intended for essentially non load-bearing stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, foot, wrist, ankle, humerus, scapula, finger, toe, pelvis, and craniomaxillofacial skeleton.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number OR K041081 Over-The-Counter Use

(Optional Format 1-2-96)