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510(k) Summary of Safety and Effectiveness

Name, Address and Establishment Registration No.

The address and registration number of the manufacturer is as follows:

Hand Innovations, LLC
8905 SW 87 Avenue, Suite 220
Miami, FL 33176-2227
Establishment Registration No.: 9042874
Tel.: (305) 270-6899
Fax: (305) 412-8060

General Provisions

The name of the device is:

Proprietary Name	Common or Usual Name
Mini Fragment Plates	Plate Fixation Bone

Name of Predicate Devices

The device is substantially equivalent to:

- Fragment Plate System (510(k) # K041081 – July 1, 20043) – Hand Innovations, LLC.

Classification

Class II.

Performance Standards

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

Indications for Use

The proposed **Mini Fragment Plates** are intended for essentially non load bearing stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion, and reconstructions of small bones of the hand, foot, wrist, ankle, humerus, scapula, finger, toe, pelvis, and craniomax, illofacial skeleton.

Device Description

The proposed **Mini Fragment Plates** are a set of orthopedic plates and fasteners supplied in a sterilization tray together with several reusable and disposable tools. The set of orthopedic plates and fasteners provided in the sterilization tray consists of the following implantable devices:

- Fragment Plates that are provided in the following design configurations:
  - Straight,
  - Y,
  - Right Hockey Stick, and
  - Left Hockey Stick.
- Pegs;
- Screws; and
- K-Wires.

Included in the sterilization tray are the following re-useable instruments:

- Peg drivers,
- Other standard surgical tools.

In addition, the following are non-reusable instruments included in the sterilization tray:

- F.A.S.T. Guide Technology™ Drill Guide,
- Drill bits.

Biocompatibility

The Proposed **Mini Fragment Plates** do not require biocompatibility testing because the material is the same as the previously approved **Fragment Plate System**. The material is Ti-6Al-4V ELI per ASTM F 136-00 and also has a long history of safe use in the Orthopedic industry.

Summary of Substantial Equivalence

The proposed **Mini Fragment Plates** has the following similarities to the previously cleared **Fragment Plate System** : (K041081).

- Have the same indications for use and intended use
- Have the same basic shape/design
- Use the same operating principle
- Utilize the same materials

In summary, the changes incorporated in the proposed **Mini Fragment Plates** do not alter the fundamental scientific technology of the predicate device and therefore, in our opinion, is substantially equivalent to the predicate **Fragment Plate System.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Hand Innovations, LLC
% DePuy Orthopaedics, Inc.
Ms. Natalie S. Heck
Manager of Regulatory Affairs
700 Orthopaedic Drive
PO Box 988
Warsaw, Indiana 46581

JUL 17 2006

Re: K061748
Trade/Device Name: Mini Fragment Plates
Regulation Number: 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulation Class: II
Product Code: KTT
Dated: June 19, 2006
Received: June 21, 2006

Dear Ms Heck:

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 (240) 276-0120 . 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 (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

K061748

Indications for Use

510(k) Number (if known): _____
Device Name: **Mini Fragment Plates**

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 reconstructions of small bones of the hand, foot, wrist, ankle, humerus, scapula, finger, toe, pelvis, and craniomax, illofacial skeleton.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ruch MD for MKM

(Division Sign-Off)

(Posted November 13, 2003)

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Division of General, Restorative and Neurological Devices

510(k) Number K061748