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Amendments to K060294 – Hand Innovations Diaphyseal Plate 20 March 2006

510(k) Summary of Safety and Effectiveness

General Provisions

The name of the device is:

Proprietary Name	Common or Usual Name
Hand Innovations Diaphyseal Plate	Plate Fixation Bone

Name of Predicate Devices

The proposed **Diaphyseal Plate** is substantially equivalent to the following predicate device:

- 3.5mm LCP® Plate – SYNTHES (USA) (510(k) No. K000684- April 28, 2000).

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 **Diaphyseal Plate** is intended for the fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, pelvis, distal tibia, and fibula, particularly in osteopenic bone.

Device Description

The proposed **Diaphyseal Plate** is fabricated from 316L Stainless Steel and is available in five configurations – 6, 8, 10, 12, and 14 hole plate configuration. The proposed **Diaphyseal Plate** has both slotted holes, for accommodating the Multi-Directional Screws, and round holes for accommodating either Multi-Directional or 90° Lock Screws. 90° Set Screws are used to secure the 90° Lock Screws within the plate to prevent backout.

Biocompatibility

The proposed **Diaphyseal Plate** do not require biocompatibility testing because 316L stainless steel is used in all fabrications per the requirements of ASTM F 138-03. 316L is universally regarded as biocompatible and suitable for surgical implant per the requirements of ISO 10993-1.

Summary of Substantial Equivalence

The proposed **Diaphyseal Plate** is substantially equivalent to the predicate competitive 3.5mm LCP® Plate SYNTHES (USA) with regards to the intended use, materials, biocompatibility, and overall performance characteristics. The equivalence was confirmed through pre-clinical testing. See Section 8 Performance Testing for a summary of tests used to demonstrate safety and effectiveness of the proposed device. Attachment 9 Engineering Test Protocol and Report presents the detailed test results demonstrating safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2006

Hand Innovations, LLC
c/o Mr. Richard Jones
QA Manager
8905 SW 87th Avenue
Suite 220
Miami, Florida 33176

Re: K060294
Trade/Device Name: Hand Innovations Diaphyseal Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: February 1, 2006
Received: February 7, 2006

Dear Mr. Jones:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

K060294

510(k) Number (if known): _____

Device Name: **Diaphyseal Plate**

Indications for Use Statement

The **Diaphyseal Plate** is intended for the fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, pelvis, distal tibia, and fibula, particularly in osteopenic bone.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___√___ OR Over-The-Counter Use _____

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

510(k) Number K060294