JUL 20 2005

K051728

510(k) Summary of Safety and Effectiveness

General Provisions

The name of the device is:

Proprietary Name	Common or Usual Name
Modified Shoulder Fixation System	Plate Fixation Bone

Name of Predicate Devices

The device is substantially equivalent to:

- Shoulder Fixation System (510(k) # K042059 – September 30, 2004) – Hand Innovations, Inc.

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 **Modified Shoulder Fixation System** is intended for fractures and fracture dislocations, osteotomies, and non-unions of the proximal Humerus.

Device Description

The **Modified Shoulder Fixation System** is 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:

- Shoulder Plates
- Multidirectional and 90° Lock Screws
- 90° Set Screws
- Pegs

Also, provided in the sterilization tray are the re-useable instruments

Biocompatibility

The implantable components of the **Modified Shoulder Fixation System** and instruments do not require biocompatibility testing because the stainless steel used in fabrications meets the requirements of ASTM F 138.

Summary of Substantial Equivalence

The **Modified Shoulder Fixation System** is substantially equivalent to the predicate Shoulder Fixation System. The equivalence was confirmed through pre-clinical testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 2005

Mr. Ernesto Hernandez
Vice President RA/QZ
Hand Innovations, LLC
8905 SW 87TH Avenue, Suite 220
Miami, Florida 33176

Re: K051728
Trade/Device Name: Shoulder Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: LXT
Dated: June 24, 2005
Received: June 27, 2005

Dear Mr. Hernandez:

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,

for Miriam C. Provost, Ph.D
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Shoulder Fixation System

Indications for Use Statement

The **Modified Shoulder Fixation System** is intended for fractures and fracture dislocations, osteotomies, and non-unions of the proximal Humerus.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

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

510(k) Number K051728