DEC 0 5 2002

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510(k) Summary of Safety and Effectiveness

1. **Manufacturer and Contact Information:**

Manufacturer & U. S. Distributor	Hand Innovations, Inc. 8905 S. W. 87th Avenue Miami, FL 33175-2227
Contact Information:	Richard D. Bliss, Jr. Quality Systems Engineering 510 Stonemont Drive Weston, FL 33326 Telephone: (954) 385-1690 Fax: (954) 385-1256

2. **Device Classification Name**:
The Orthopedic Devices Panel has classified the single/multiple component metallic bone fixation appliances and accessories as Class II. Reference 21 CFR 888.3030.

3. **Intended Use:**
The Distal Radius Fracture Repair Kit is intended for the fixation of fractures and osteotomies involving the distal radius.

4. **Device Description and Characteristics**
This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) 1990 and the FDA Modernization Act of 1997 (FDAMA).

The Distal Radius Fracture Repair System consists of the Distal Volar Fracture Repair System, which was previously cleared under 510(k) No. K002775. The system comprises volar stabilization plate, bone, screws, and fixation pegs. This 510(k) is being submitted as a modification to the original 510(k) No. K002775 to allow for the dorsal fixation of stable fractures of the distal radius. A copy of the clearance letter is enclosed with this submission.

The Distal Dorsal Nail Plate (DNP) (left and right) is an implantable orthopedic nail-plate device used for the fixation of distal radius fractures. This device permits fixation of distal radius fractures with a minimal incision on the dorsal side while avoiding the tendon adhesion problems. The device consists of a plate portion, which offsets into a nail portion, all cut out of a solid piece of titanium (Titanium TI-6AL-4V ELI anodized Type II). The plate portion is narrow (~6mm) and long (~16mm) and has 3 threaded holes for the attachment of pegs with bending load capacity. These holds are appropriately angled so the pegs fan out and support the distal fracture fragment near the articular surface. The nail portion starts thick and tapers into a long, flexible section. At the start of the taper there are 2 crossing holes spaced about 9 mm apart. The holes are sized to fit 2.5 mm screws, which are used to anchor the nail-plate to the radius proximal of the fracture. The pegs, standard or threaded, and the 2.5mm screws

are driven with the Peg Driver. The anchor screws and pegs are available in different lengths to accommodate most patient anatomies and fracture morphologies.

Other components used in the implantation process are identified as the DNP Jig Set of Stainless Steel SST 17-4. These items consist of the DNP Jig (left or right), drill guide, screw jig and screw guide.

A standard awl, which is a manual tool, used to increase the size of a hole or tunnel by scraping in rotation is a standard catalog item manufactured by from K-Medic under catalog no. KM-48-336.

The components of this system will be packaged together and will also be available individually. The materials used for the various components in Distal Dorsal Nail Plate and Jig Set include the following:

Name	Part No.	Material Composition
Dorsal Nail Plate Right	DRW-067	Titanium TI-6AL-4V ELI
Dorsal Nail Plate Left	DRW-054	Titanium TI-6AL-4VELI
Peg Volar Plate (14,16,18,20,22,24,26,28mm)	DRW-005/ 010, DRW-055/DRW-056 (Table DRW-20)	Titanium TI-6AL-4V ELI
Threaded peg 2.5 mm (14,16,18,20,22,24,26,28mm)	DRW-028/ 033, DRW-057/DRW-058 (Table DRW-026)	Titanium TI-6AL-4V ELI
Screw, 2.5mm (14,16,18, 20,22,24,26,28mm)	DRW-034/ 039, DRW-059/DRW-060 (Table DRW-027)	Titanium TI-6AL-4V ELI
Peg Driver Assembly	DRW-016	Stainless Steel 440C
Drill Guide	DRW-017	Stainless Steel 440C
DNP Jig, Left	DRW-062	Stainless Steel SST-17-4
DNP Jig, Right	DRW-063	Stainless Steel SST-17-4
DNP Screw Jig	DRW-064	Stainless Steel SST-17-4
DNP Screw Guide	DRW-065	Stainless Steel SST-17-4
DNP Drill Guide	DRW-066	Stainless Steel SST-17-4
Depth Gauge	Supplied by K-Medic	Off the shelf catalog item.
Drill, 2.0mm	Supplied by Microaire	Off the shelf catalog item.
Awl	Supplied by K-Medic	Off the shelf catalog item.

Name	Part No.	Material Composition
Screw Holding Sleeve	Supplied by K-Medic	Off the shelf catalog item.
Drill, 2.5 mm	Supplied by Microaire	Off the shelf catalog item.
Drill, 1.8 mm	Supplied by Microaire	Off the shelf catalog item.
Hex Driver	Supplied by K-Medic	Off the shelf catalog item.
Plate Bender	Supplied by K-Medic	Off the shelf catalog item.
Tissue Guide	Supplied by K-Medic	Off the shelf catalog item.
Screw Rack	DRW-018	Not a device.
Sterilization Tray	DRW-019	Not a device.

The components within this system will be provided as non-sterile for steam sterilization by health care professionals prior to use. Instructions for sterilizations are contained in the package insert. The kit components will also be available separately provided as non-sterile for steam sterilization by the healthcare professional.

The system is packaged in a high tempered plastic sterilization tray. The tray is provided with inserts to retain the components. The tray is placed in a polymeric bag and placed into a shipping carton. All components sold separately are packaged in polymeric pouches.

See Modification of Device Section for the Kit Manufacturer's Certification Statement containing a complete listing of all components.

5. Substantial Equivalence

Hand Innovations Inc. considers the modifications to this Distal Radius Fracture Repair System to be substantially equivalent to the Synthes Distal Radius Plate System, 510(k) No. K982732, with regard to the intended use, materials, biocompatibility and overall performance characteristics. The current labeling for the Distal Volar Radius Fracture Repair System has been modified to include the components for the Distal Dorsal Nail Plate. As previously mentioned, the name of the combined product has changed to accommodate this modification.

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Summary of Substantial Equivalence

Feature	Distal Radius Fracture Repair Kit	Distal Radius Plate Instrument and Implant Set (Predicate Device)
Manufacturer	Hand Innovations, Inc.	Synthes USA
Packaging	Tempered Plastic suitable for steam sterilization	Stainless steel tray suitable for steam sterilization
Sterilization method	Provided non -sterile Recommend steam sterilization	Provided non-sterile Recommend steam sterilization
Intended use	Distal Radius Fracture Repair System is intended for the fixation of fractures and osteotomies involving the distal radius.	The Synthes Distal Radius Plate System is intended for fixation of fractures, osteotomies, including carpal fusions involving the distal radius applied to the volar and dorsal aspects.
Implant Period	Permanent	Permanent
Material of Construction	Plates: Titanium Pegs and Screws: Titanium and Stainless Steel	Plates: Stainless Steel and Titanium Alloy Pegs and Screws: Stainless Steel and Titanium Alloy
Available configurations	Right and Left Volar and Dorsal	Right and Left Volar and Dorsal
No. of buttress pegs	5 each size	6 maximum
No. of Cortex Screws	8 each size	6 maximum
Buttress Peg Length mm	16, 18, 20, 22, 24, 26, 28	Trim to desired length
Cortex Screw Length mm	10, 12, 14, 16, 18	10 to 26
Specialized instruments included in tray	Bending tool Drill Guide Depth Gauge Peg Driver Screw Driver DNP Jig Right & Left	Bending Pliers and Irons Drill Guide Depth Gage Peg Driver Screw Driver
Tool and component separators and holders in tray	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 5 2002

Hand Innovations, Inc.
c/o Mr. Richard D. Bliss, Jr.
Quality Systems Engineering, Inc.
510 Stonemont Drive
Weston, Florida 33326

Re: K023007
Trade/Device Name: Distal Radius Fracture Repair System
Regulation Numbers: 21 CFR 888.3030
Regulation Names: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: September 4, 2002
Received: September 9, 2002

Dear Mr. Bliss:

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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

K023007

Device Name:

Distal Radius Fracture Repair System

(The original name for this device, Distal Volar Radius Fracture Repair System that cleared FDA under 510(k) No. K002775, is being modified to accommodate both the Volar and the Dorsal fixation of distal radius fractures.)

Indications for Use:

The Distal Radius Fracture Repair System is intended for the fixation of fractures and osteotomies involving the distal radius.

This 510(k) submission will address the only the additional indication for use

(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_____
(Pre 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023007

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