APR 0 1 2003

K030198
page 1 of 4

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 was previously cleared under 510(k) No. K023007. The system consists of a volar stabilization plate, bone screws, fixation pegs, dorsal intrafocal nail-plate, three fixed angle bone pegs and two locking screws. This 510(k) is being submitted as a modification to the original 510(k) No. K023007 to update and standardize the sterilization cycle. A copy of the clearance letter is enclosed with this submission.

The Distal Volar Radius Plate (DVR) consists of a stabilization plate, bone screws, and fixation pegs. The 3.5 mm screws are used to affix the proximal segment of the plate to the diaphysis. Pegs or screws are used for the distal bone fragment(s).

The Distal Dorsal Nail-Plate (DNP) is a bone stabilization device consisting of an intrafocal nail-plate to which three-fixed angle bone pegs and two locking screws are attached. It has a narrow distal plate-like section that lies on the surface of the distal fragment and a proximal nail-like section that is introduced into the diaphysis of the radius through the fracture site. Fixed angle pegs are used to fix the distal fragment(s) to the plate section and locking screws are used to lock the proximal fragment inside the radial shaft.

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 Radius Fracture Repair System include the following:

Name	Part No.	Material Composition
Volar Plate, Right		Titanium TI-6AL-4V ELI
Volar Plate, Left		Titanium TI-6AL-4V ELI
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 Distal Radius Fracture Repair System, 510(k) No. K023007 that cleared FDA on December 5, 2002, with regard to the intended use, materials, biocompatibility and overall performance characteristics. The current labeling for the Distal Radius Fracture Repair System has been revised to reflect the change in the sterilization cycle.

K030198
page 4 of 4

Summary of Substantial Equivalence

Feature	Distal Radius Fracture Repair Kit	Distal Radius Fracture Repair Kit (Predicate Device)
Manufacturer	Hand Innovations, Inc.	Hand Innovations, Inc.
Packaging	Tempered Plastic suitable for steam sterilization	Tempered Plastic suitable For stem 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.	Distal Radius Fracture Repair System is intended for the fixation of fractures and osteotomies involving the distal radius.
Implant Period	Permanent	Permanent
Material of Construction	Plates: Titanium Pegs and Screws: Titanium and Stainless Steel	Plates: Titanium Pegs and Screws: Titanium And Stainless Steel
Available configurations	Right and Left Volar and Dorsal	Right and Left Volar and Dorsal
No. of buttress pegs	5 each size	5 each size
No. of Cortex Screws	8 each size	8 each size
Buttress Peg Length mm	16, 18, 20, 22, 24, 26, 28	16, 18, 20, 22, 24, 26, 28
Cortex Screw Length mm	10, 12, 14, 16, 18	10, 12, 14, 16, 18
Specialized instruments included in tray	Bending tool Drill Guide Depth Gauge Peg Driver Screw Driver DNP Jig Right & Left	Bending Tool Drill Guide Depth Gage Peg Driver Screw Driver DNP Jig Right & Left
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

APR 01 2003

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

Re: K030198
Trade Name: Distal Radius Fracture Repair System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: January 20, 2003
Received: January 21, 2003

Dear Mr. Bliss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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,

for Mark N. Melkerson

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

K030198

Device Name:

Distal Radius Fracture Repair System

Indications for Use:

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

(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 Milhern

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

510(k) Number K030198