

JUN 23 1999

**Summary of Safety and Effectiveness  
for the  
Metacarpal Fixation System**

*Submitted by*

K991064

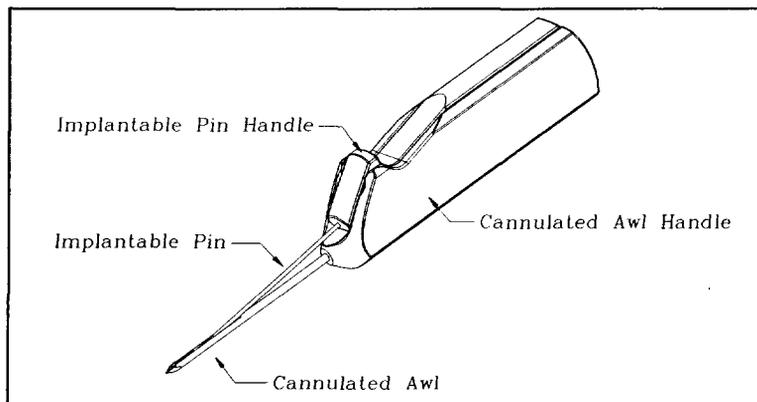
Medcanica, Inc.  
8308 NW 74th Avenue  
Miami, FL 33166  
Phone: (305) 863-1603

### Identification of a Legally Marketed Predicate Device

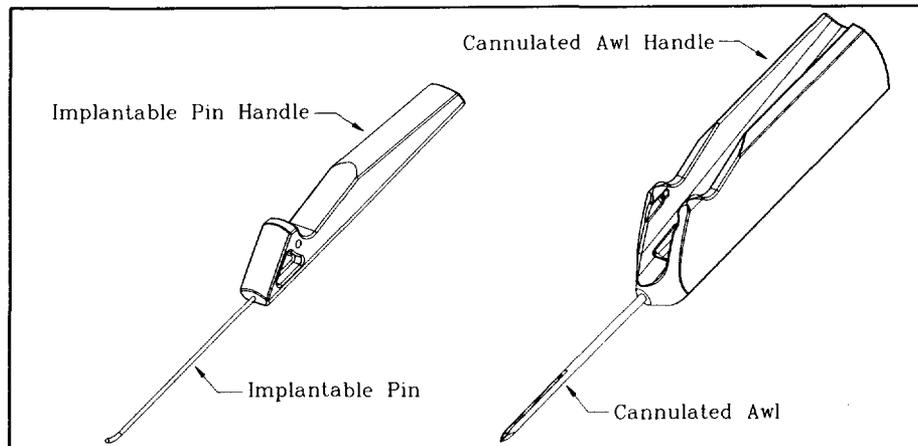
The Medcanica, Inc. Metacarpal Fixation System (MFS) is substantially equivalent to the K-wire implantable pin that is manufactured and marketed by MicroAire Surgical Equipment, Inc.

### Device Description

The MFS is a sterile, single use, disposable device that is delivered non-toxic. The MFS consists of the Cannulated Awl Assembly, the Implantable Pin Handle Assembly, and Exchange Guide and Bend Tube. A typical MFS is shown in Figure 1, MFS Assembled Implantable Pin Handle and Cannulated Awl Assemblies. Figure 2, Implantable pin and Awl Assemblies shows the assemblies separately.



**Figure 1, MFS Assembled Implantable Pin Handle and Cannulated Awl Assemblies**



**Figure 2, Implantable Pin and Awl Assemblies**

Prior to use the implantable pin assembly is nested in the cannulated awl assembly. The cannulated awl assembly has a trocar point. The implantable pin has a blunt point that is positioned just behind the trocar point of the cannulated awl. The sharp point of the cannulated awl assembly is passed through a small incision. A hole is drilled into the metacarpal bone by twisting the assembled handles back and forth. After gaining access to the intramedullary space, the cannulated awl handle is held stationary while the implantable pin is then advanced distally from the base of the metacarpal bone. See Figure 3, MFS Partially Deployed.

The awl handle is then withdrawn and removed for advancement of the implantable pin. The implantable pin is then cut adjacent to the pin handle. Using the bending tube end of the exchange guide and bend tube pictured in Figure 4, Exchange Guide and Bend Tube, the implantable pin is bent to 90° with the apex of the bend at the implantable pin insertion site. The pin is trimmed so that the end is below the skin. The small piece remaining will facilitate removal of the implantable pin subsequent to healing. The implantable pin will remain implanted for approximately six weeks. Upon healing of the fracture, the implantable pin is percutaneously removed.

In the event that it is desired to reform the implantable pin or implant a smaller pin, this may be accomplished without losing access to the medullary canal. The exchange guide is advanced along the implantable pin into the medullary space. Once the medullary space is accessed, the pin is removed. Another pin may be placed into the medulla by inserting it into the groove of the exchange guide. After the pin has been inserted into the medullary space, remove the exchange guide.

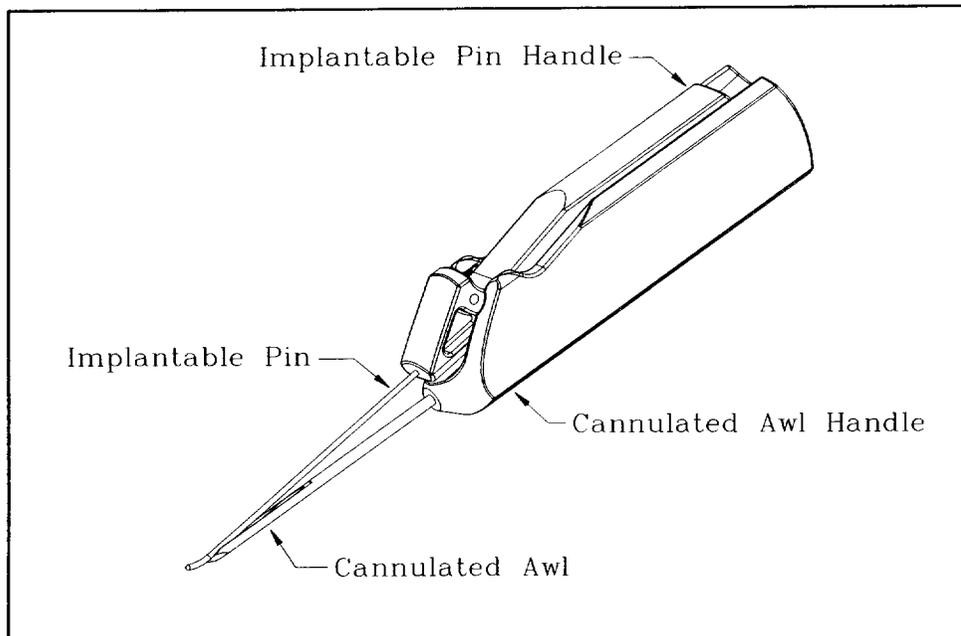


Figure 3, MFS Partially Deployed

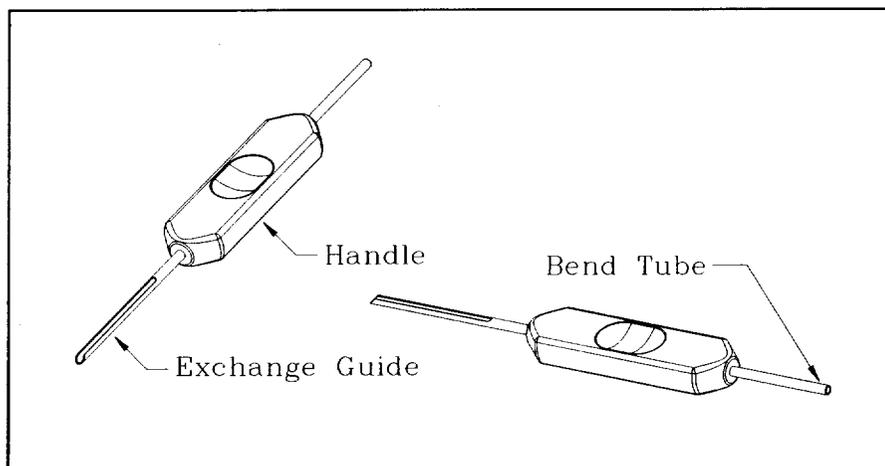


Figure 4, Exchange Guide and Bend Tube

**Intended Use**

The Metacarpal Fixation System is indicated for the fixation of transverse or short oblique fractures of the diaphysis or diaphyseal-metaphyseal junction of metacarpal bones.

### Summary of Technological Characteristics

The table below compares the technological characteristics of the MFS to the predicate device.

Feature	MFS	Predicate Device
Manufacturer	Medcanica, Inc.	MicroAire
Sterile packaging	Tray, Mylar®/Tyvek® Pouch	Polymeric Pouch
Sterilization method	Gamma radiation	Gamma radiation
Shelf life	3 years	3 years
Intended use	The Metacarpal Fixation System is indicated for the fixation of transverse or short oblique fractures of the diaphysis or diaphyseal-metaphyseal junction of metacarpal bones.	Used in a variety of surgical applications including metacarpal fixation.
Implant Period	Approximately 6 weeks	Various including permanent
Drill geometry†		
Facets	3	3
Edge Angle	23.5°	19.0°
Facet Angle	13.7°	10.4°
Working length*	3.5 inches	6.0 inches
Available Sizes	0.062	0.062
Implantable pin material	316LVM, ASTM F138-97	316LVM, ASTM F138-97
Placement Method‡	Cannulated Awl	Powered Drill

† The Metacarpal Fixation System has a different drill geometry than the predicate because it is designed to be compliant with the trocar point requirements of ISO 5838-3, Implants for Surgery — Skeletal Pins and Wires — Part 3: Kirschner Skeletal Wires.

\* Working length of the Metacarpal Fixation System has a shorter working than the predicate device because it is not a multi-purpose device. It needs only to accommodate the length of metacarpal bones.

‡ Placement of implantable pins in the metacarpal bone does not require the use of a powered drill. Because the Metacarpal Fixation System is restricted to metacarpal use it is not designed for use with a powered drill.

### **Summary of Performance Data**

The MFS meets the requirements of the following recognized consensus standards.

- ASTM F138 – 97, Standard Specification for Wrought 18 Chromium–14 Nickel–2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)
- ASTM F899 – 95, Standard Specification for Stainless Steel Billet, Bar and Wire for Surgical Instruments
- ASTM F86 – 91, Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants
- ASTM F366 – 82 (Reapproved 1993), Standard Specification for Fixation Pins and Wires

The MFS is substantially equivalent to the K-wire manufactured by MicroAire Surgical Equipment, Inc. Extensive bench testing of both devices has demonstrated this. Testing includes stiffness/yield, cutting geometry comparison, and drilling test.

The tissue/bone contact materials of the device have been carefully selected for their long history of biocompatibility. The materials meet the requirements of the previously referenced recognized consensus standards.

Since the MFS meets the requirements of the stated standards and embodies technological characteristics essentially identical to the predicate device, we believe the device is safe and effective and performs as well as or better than the predicate device. The MFS was designed utilizing design controls compliant with the Quality System Regulation. The MFS will be manufactured per specifications and good manufacturing practices that ensure the device is safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 23 1999

Mr. Matthew A. Palmer  
President  
Medcanica, Inc.  
8308 NW 74<sup>th</sup> Avenue  
Miami, Florida 33166

Re: K991064  
Trade Name: Metacarpal Fixation System  
Regulatory Class: II  
Product Code: HTY  
Dated: March 30, 1999  
Received: March 31, 1999

Dear Mr. Palmer:

We have reviewed your Section 510(k) 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). 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.

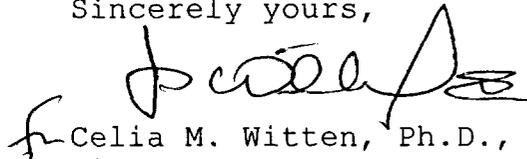
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Matthew A. Palmer

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

  
f Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

Page 1 of 1

510(k) Number (if known): K991064

Device Name: Metacarpal Fixation System

Indications for Use:

The Metacarpal Fixation System is indicated for the fixation of transverse or short oblique fractures of the diaphysis or diaphyseal-metaphyseal junction of metacarpal bones.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division **Sign-Off**)  
Division of **General Restorative Devices**  
510(k) Number K991064

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)