

**Summary of Safety and Effectiveness As Required by 807.92(c)
for the
Phalangeal Fixation System**

MAR - 1 2000

Submitted by

Medcanica, Inc.
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Contact Person: Sonia Jones

Device Trade Name: Phalangeal Fixation System

Common Name: K-Wire

Classification Name: Smooth or threaded metallic bone fixation fastener, per § 888.3040

Identification of a Legally Marketed Predicate Device

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

Device Description

The PFS is a single use, non-toxic, disposable, sterile device. The PFS consists of the Cannulated Awl Assembly, the Implantable Pin Handle Assembly, and Exchange Guide and Bend Tube.

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 Phalangeal 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 phalangeal bone.

The awl handle is then withdrawn and removed for advancement of the implantable pin. Multiple pins, usually two, are implanted in the manner previously described. The pins are placed in a arrangement to minimize radial movement.

The implantable pin(s) is then cut at the taper near the proximal end of the pin. Using the bending tube end of the exchange guide 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.

Intended Use

The Phalangeal Fixation System is indicated for the fixation of transverse or short oblique fractures of proximal phalanx of the fingers.

Summary of Technological Characteristics

The PFS is substantially equivalent to the K-wire manufactured by MicroAire Surgical Equipment, Inc. This has been demonstrated through comparison of eleven technological characteristics.

Summary of Performance Data

Five performance characteristics of the PFS and K-wire manufactured by MicroAire Surgical Equipment, Inc. have been compared. Analysis of the data shows the products to be substantially equivalent.

Conclusion

The PFS has been demonstrated to be equivalent to the and K-wire manufactured by MicroAire Surgical Equipment, Inc. by extensive bench testing of both devices and comparison of technological characteristics.

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

The PFS was designed utilizing design controls compliant with the Quality System Regulation. The PFS will be manufactured per specifications and good manufacturing practices that ensure the device is safe and effective for its intended use.



MAR - 1 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Al Weisenborn
MEDCANICA, Inc.
19526 East Lake Drive
Miami, Florida 33015

Re: K994232
Trade Name: Phalangeal Fixation System
Regulatory Class: II
Product Code: HTY
Dated: December 15, 1999
Received: December 16, 1999

Dear Mr. Weisenborn:

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 control provisions of the Act. The general control 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.

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.

Page 2 - Mr. Al Weisenborn

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 at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Str James E. Dillard III
Acting 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): K 994232

Device Name: Phalangeal Fixation System

Indications for Use:

The Phalangeal Fixation System is indicated for the fixation of transverse or short oblique fractures of proximal phalanx of the fingers.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Russell Payne
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 994232

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)