

DEC 4 1998

K983881

#### Appendix 4

### Summary of Safety and Effectiveness

**Submitter:** Orthopedic Innovations, Inc.  
6188 Olson Memorial Highway  
Minneapolis, MN 55422  
Telephone: (612) 591-0001

**Product:** Classification Name: Single/multiple component metallic bone fixation appliances and accessories  
(21 CFR 88.3030)  
Common Name: External Fixation System  
Trade/Proprietary Name: Cobra External Fixator

**Substantially Equivalent Products:** Orthopaedic Innovations Practifix (K960014), Synthes AO/ASIF and Howmedica Mini Hoffman External Fixation Systems

**Description:** The device a two-piece hinged external fixator. Set-screws are used to secure orthopedic pins or K-wires to the fixator and establish the fixation angle.

**Intended Use:** The intended use is similar to that for other external fixation systems.

**Comparison to Substantial Equivalent Products:** All devices have the same intended use, principle or operation and material requirements. Differences between the new and other predicate devices do not affect safety and effectiveness.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Todd J. Hein  
Vice President  
Orthopaedic Innovations  
6188 Olson Memorial Highway  
Golden Valley, Minnesota 55422

Re: K983881  
Cobra External Fixator  
Regulatory Class: II  
Product Code: HRS  
Dated: October 28, 1998  
Received: November 2, 1998

Dear Mr. Hein:

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.

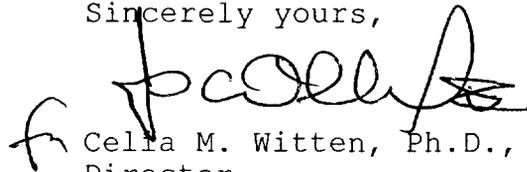
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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

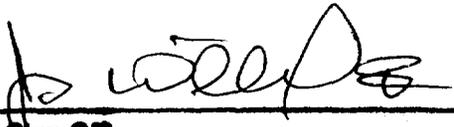
Enclosure

## Appendix 2

### Intended Use

The Cobra device is designed to externally connect and stabilize pins and/or k-wires inserted into bone fragments allowing the fragments to heal in the proper orientation. The device is intended for fractures near the wrist joint, specifically fractures of the distal extremity of the radius, to include; extra-articular fractures, intra-articular fractures and impacted or die-punch fractures.

Prescription Use X  
(Per 21 CFR 801.109)

  
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(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number 2903881