

JUN 27 1997

K971682

# Johnson & Johnson

## PROFESSIONAL, INC.

### 510(k) Summary

Johnson & Johnson Professional, Inc.  
325 Paramount Drive  
Raynham, MA 02767-0350

Contact Person: John D. Ferros  
Phone: (508) 880-8287  
Fax: (508) 828-3212

#### Name of Device

*Classification Name:* Bone Fixation Cerclage has been placed in Class II by the FDA under 21 CFR 888.3010. This falls under the Orthopaedics panel/87.

*Common Name:* Cerclage Fixation Device.

*Trade Name/Proprietary Name:* **J-Fx Cerclage System**

*Performance Standards:* No performance standards have been developed for this device.

#### Predicate Device

- OSTEO-CLAGE™ Cable system by Acumed, Inc. (K921480)
- DALL-MILES Trochanter Cable Grip System by Howmedica. (K934058)
- FX-CABLELOK™ System by Biodynamic Technologies, Inc. (K935646)

#### Description of Device

The J-Fx Cerclage System consists of implants and instruments. The implants are cables and sleeves in both stainless steel and cobalt chromium alloy. The cables are available in two diameters, 1.6 mm and 2.0 mm. Instrumentation is also part of the system to assist in the placement of the implants.

#### Intended Use

The J-Fx Cerclage System is indicated for use in general orthopaedic repairs. This includes such procedures as reinforcement of bone, reattachment of the greater trochanter, fixation of long bone fracture with grafting, fixation of patellar fractures, and closure of sternum following open heart surgery.

## Technological Characteristics Compared to Predicate Device

### Similarities and Differences Matrix

	J-Fx	OSTEO-CLAGE	DALL-MILES	FX-CABLELOK
<b>Design</b>				
Flexible Cable	Yes	Yes	Yes	Yes
Fixation Method	Crimped Sleeve	Crimped Sleeve	Crimped Sleeve	Crimped Sleeve
Chamfered Sleeve Hole Edges	Yes	Yes	?	?
Cable Thickness	2mm or 1.6mm	2mm or 1.6mm	2mm or 1.6mm	2mm
<b>Uses:</b>				
Cable Passer	Yes	Yes	Yes	Yes
Cable Tensioner	Yes	Yes	Yes	Yes
Sleeve Crimper	Yes	Yes	Yes	Yes
Cable Cutter	Yes	Yes	Yes	Yes
<b>Materials</b>				
Cable	Co-Cr or SS	Co-Cr or SS	Vitallium®	Co-Cr
Sleeve	Co-Cr or SS	Co-Cr or SS	Vitallium®	Co-Cr



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. John D. Ferros  
Senior Regulatory Affairs Specialist  
Johnson & Johnson Professional, Inc.  
325 Paramount Drive  
Raynham, Massachusetts 02767

JUN 27 1997

Re: K971682  
J-Fx Cerclage System  
Regulatory Class: II  
Product Code: LRN  
Dated: May 5, 1997  
Received: May 6, 1997

Dear Mr. Ferros:

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 (Pre-market 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 pre-market 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. John D. Ferros

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,

*for* *Maria A. Schroeder, MS, PT*  
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

510(k) Number (if known): K971682

Device Name: **J-Fx Cerclage System**

Indications for Use:

The J-Fx Cerclage System is indicated for use in general orthopaedic repairs. This includes such procedures as reinforcement of bone, reattachment of the greater trochanter, fixation of long bone fracture with grafting, fixation of patellar fractures, and closure of sternum following open heart surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Maie Schneider MSPT for CDRH  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K971682

Prescription Use X  
(Per 21 CFR 801.109)

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

(Optional Format 1-2-96)