

**K945793 P.F.C.(R) BIPOLAR HIP SYSTEM - 22MM BIPOLAR**Apr 10, 1995  
136 days to decisionK945793 · Product code: **KWY** · Orthopedic  
Source: <https://www.510kdatabase.net/k945793/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	Nov 25, 1994
Decision date	Apr 10, 1995
Days to decision	136 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Johnson &amp; Johnson Professionals, Inc.</b>
Location	Raynham, MA, US
Contact	J T DORRIETY
Website	<a href="https://www.jnj.com">https://www.jnj.com</a>
510(k) history	206 submissions · 184 cleared · 1976-2000

Johnson & Johnson Professionals, Inc. is a medical device company based in Raynham, Massachusetts. The company specializes in surgical and orthopedic devices. The company has received FDA 510(k) clearances from total submissions between 1976 and 2000. Orthopedic devices and neurosurgical instruments represent core product categories. Notable cleared devices include hip and elbow prostheses, programmable valve systems, and aneurysm clips. The company is inactive and represents a historical regulatory record with no submissions in more than two decades. Explore the complete...

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