

**K970194 PROFORM CEMENTED TITANIUM REVISION  
FEMORAL COMPONENT**Apr 14, 1997  
83 days to decisionK970194 · Product code: JDI · Orthopedic  
Source: <https://www.510kdatabase.net/k970194/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Jan 21, 1997
Decision date	Apr 14, 1997
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Stelkast Company</b>
Location	Pittsburgh, PA, US
Contact	DONALD A STEVENS
510(k) history	40 submissions · 37 cleared · 1994-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970194/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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