

**K971715 SELECT SHOULDER OFFSET HUMERAL HEAD COMPONENTS**Aug 7, 1997  
90 days to decisionK971715 · Product code: **KWS** · Orthopedic  
Source: <https://www.510kdatabase.net/k971715/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	May 9, 1997
Decision date	Aug 7, 1997
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sulzer Orthopedics, Inc.</b>
Location	Austin, TX, US
Contact	JACQUELYN HUGHES
510(k) history	45 submissions · 41 cleared · 1997-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971715/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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