

K003758 ALLOFIT ACETABULAR SYSTEMMar 7, 2001
91 days to decisionK003758 · Product code: **KWA** · Orthopedic
Source: <https://www.510kdatabase.net/k003758/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained (metal Uncemented Acetabular Component) (KWA)
Date received	Dec 6, 2000
Decision date	Mar 7, 2001
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sulzer Orthopedics, Inc.
Location	Austin, TX, US
Contact	MITCHELL A DHORITY
510(k) history	45 submissions · 41 cleared · 1997-2002

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