

**K003728 MODIFICATION TO AEQUALIS SHOULDER
FRACTURE SYSTEM**Dec 20, 2000
16 days to decisionK003728 · Product code: **KWS** · Orthopedic
Source: <https://www.510kdatabase.net/k003728/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Dec 4, 2000
Decision date	Dec 20, 2000
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tornier
Location	Concord, CA, US
Contact	DAVID W SCHLERF
510(k) history	44 submissions · 44 cleared · 1995-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003728/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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