

K980244 AEQUALIS SHOULDER PROSTHESISAug 23, 1999
577 days to decisionK980244 · Product code: **KWS** · Orthopedic
Source: <https://www.510kdatabase.net/k980244/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Jan 23, 1998
Decision date	Aug 23, 1999
Days to decision	577 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/k980244/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026