

**K043077 MODIFICATION TO AEQUALIS SHOULDER
FRACTURE SYSTEM**Dec 17, 2004
39 days to decisionK043077 · Product code: **KWS** · Orthopedic
Source: <https://www.510kdatabase.net/k043077/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Nov 8, 2004
Decision date	Dec 17, 2004
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary
Other names	AEQUALIS SHOULDER SYSTEM

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k043077/> 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