FDA 510(k) Premarket Notification

K102924 AEQUALIS ASCEND MODULAR ANATOMIC SHOULDER SYSTEM

CLEARED

Jan 31, 2011
123 days to decision

K102924 · Product code: **KWS** · Orthopedic
Source: https://www.510kdatabase.net/k102924/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Sep 30, 2010
Decision date	Jan 31, 2011
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Tornier, Inc.**
Location	Beverly, MA, US
Contact	BRAHIM HADRI
510(k) history	51 submissions · 51 cleared · 2000-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k102924/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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