

K103007 AFFINITI TOTAL AND HEMI-SHOULDER SYSTEMNov 9, 2010
28 days to decisionK103007 · Product code: **KWS** · Orthopedic
Source: <https://www.510kdatabase.net/k103007/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Oct 12, 2010
Decision date	Nov 9, 2010
Days to decision	28 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

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