

K103104 SPECIAL ORTHOPAEDIC SOLUTIONS GLENOID SHOULDER COMPONENTNov 22, 2010
33 days to decisionK103104 · Product code: **KWS** · Orthopedic
Source: <https://www.510kdatabase.net/k103104/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Oct 20, 2010
Decision date	Nov 22, 2010
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Howmedica Osteonics Corp.
Location	Allendale, NJ, US
Contact	AVITAL MERL-MARGULIES
510(k) history	288 submissions · 288 cleared · 1999-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k103104/> 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 16, 2026