

**K043346 GENESIS TOTAL SHOULDER REPLACEMENT, MODEL
100-01-00**Jan 31, 2005
56 days to decisionK043346 · Product code: **KWS** · Orthopedic
Source: <https://www.510kdatabase.net/k043346/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Dec 6, 2004
Decision date	Jan 31, 2005
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genesis Medical LLC
Location	Cranbury, NJ, US
Contact	PERRY GEREMAKIS
510(k) history	1 submissions · 1 cleared · 2005-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k043346/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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