

**K012417 HYGIA HEALTH SERVICE REPROCESSED KENDALL
SCD SLEEVE, MODELS # 5329, 5330, 5345, 5480**Apr 8, 2002
252 days to decisionK012417 · Product code: **JOW** · Cardiovascular
Source: <https://www.510kdatabase.net/k012417/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Jul 30, 2001
Decision date	Apr 8, 2002
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hygia Health Services, Inc.
Location	Birmingham, AL, US
Contact	GEOFF M FATZINGER
510(k) history	14 submissions · 14 cleared · 2002-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012417/>; 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 24, 2026