

K012027 MODIFICATION TO XIA SPINE SYSTEMJul 20, 2001
22 days to decisionK012027 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k012027/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Jun 28, 2001
Decision date	Jul 20, 2001
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Howmedica Osteonics
Location	Allendale,, NJ, US
Contact	KAREN ARIEMMA
510(k) history	13 submissions · 13 cleared · 2001-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012027/> 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 18, 2026