

K013295 TIMX SPINAL SYSTEMSOct 9, 2001
7 days to decisionK013295 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k013295/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Oct 2, 2001
Decision date	Oct 9, 2001
Days to decision	7 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Depuyacromed
Location	Raynham, MA, US
Contact	LISA GILMAN
510(k) history	48 submissions · 48 cleared · 1999-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013295/> 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 20, 2026