

K962645 ISOLA TWISTER CONNECTOROct 22, 1996
106 days to decisionK962645 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k962645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Jul 8, 1996
Decision date	Oct 22, 1996
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Acromed Corp.
Location	Cleveland, OH, US
Contact	WILLIAM CHRISTIANSON
510(k) history	41 submissions · 22 cleared · 1984-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k962645/> 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 21, 2026