

K965046 ISOLA TWISTER CONNECTORMar 14, 1997
86 days to decisionK965046 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k965046/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Dec 18, 1996
Decision date	Mar 14, 1997
Days to decision	86 days
Third-party review	No

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/k965046/>; 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