

**K013775 TWINFIX INTERFRAGMENTARY COMPRESSION
SCREW SYSTEM**Jan 8, 2002
56 days to decisionK013775 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k013775/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Nov 13, 2001
Decision date	Jan 8, 2002
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Leibinger
Location	Kalamazoo, MI, US
Contact	ROBIN L ROWE
510(k) history	12 submissions · 12 cleared · 1999-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013775/> 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 19, 2026