FDA 510(k) Premarket Notification

K013775 TWINFIX INTERFRAGMENTARY COMPRESSION SCREW SYSTEM

CLEARED

Jan 8, 2002
56 days to decision

K013775 · 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