

K944092 ADDITIONAL ACCESSORIES FOR THE ORTHOFIX SYSTEMApr 4, 1995
225 days to decisionK944092 · Product code: JEC · Orthopedic
Source: <https://www.510kdatabase.net/k944092/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Component, Traction, Invasive (JEC)
Date received	Aug 22, 1994
Decision date	Apr 4, 1995
Days to decision	225 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Orthofix Srl
Location	Rockville, MD, US
Contact	ROBERT L SHERIDAN
510(k) history	36 submissions · 36 cleared · 1995-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944092/> 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