

K942359 BONE PLATE SYSTEMApr 13, 1995
331 days to decisionK942359 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k942359/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	May 17, 1994
Decision date	Apr 13, 1995
Days to decision	331 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Acu Med, Inc.
Location	Beaverton, OR, US
Contact	SHARI JEFFERS
510(k) history	48 submissions · 39 cleared · 1990-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k942359/> 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 14, 2026