

K071809 ENSPLINTRX BONE FIXATION SYSTEMFeb 21, 2008
234 days to decisionK071809 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k071809/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jul 2, 2007
Decision date	Feb 21, 2008
Days to decision	234 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sonoma Orthopedic Products, Inc.
Location	Santa Rosa, CA, US
Contact	CHARLES L NELSON
510(k) history	9 submissions · 9 cleared · 2008-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k071809/> 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 16, 2026