

**K111550 SONOMA FASTRAC CLAVICLE FRACTURE REPAIR
 DEVICE MODEL SONOMA FASTRAC XXYYY(X=DIA,
 YYY=LENGTH- IN MM)**

Aug 19, 2011
 77 days to decision

K111550 · Product code: **HSB** · Orthopedic
 Source: <https://www.510kdatabase.net/k111550/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Jun 3, 2011
Decision date	Aug 19, 2011
Days to decision	77 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.net

Device record: <https://www.510kdatabase.net/k111550/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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