

K110538 PRO FIXATION SYSTEMJul 12, 2011
137 days to decisionK110538 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k110538/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Feb 25, 2011
Decision date	Jul 12, 2011
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synovis Orthopedic & Woundcare
Location	Irvine, CA, US
Contact	AMY BOUCLY
510(k) history	3 submissions · 3 cleared · 2011-2012

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