

K050462 SBI HAND FIXATION SYSTEM (TM)Apr 26, 2005
62 days to decisionK050462 · Product code: **HRS** · Orthopedic
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Feb 23, 2005
Decision date	Apr 26, 2005
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Small Bone Innovations, LLC
Location	New York, NY, US
Contact	DONALD GUTHNER
510(k) history	4 submissions · 4 cleared · 2005-2005

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