

K061146 SBI ULNAR HEAD IMPLANTJul 19, 2006
85 days to decisionK061146 · Product code: **KXE** · Orthopedic
Source: <https://www.510kdatabase.net/k061146/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Wrist, Hemi-, Ulnar (KXE)
Date received	Apr 25, 2006
Decision date	Jul 19, 2006
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Small Bone Innovations, Inc.
Location	New York, NY, US
Contact	ROBERT HOEHN
510(k) history	20 submissions · 20 cleared · 2006-2013

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