

K081025 ISOELASTICUNov 21, 2008
225 days to decisionK081025 · Product code: **KXE** · Orthopedic
Source: <https://www.510kdatabase.net/k081025/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Wrist, Hemi-, Ulnar (KXE)
Date received	Apr 10, 2008
Decision date	Nov 21, 2008
Days to decision	225 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Remi Sciences, Inc.
Location	Lititz, PA, US
Contact	SANJIV H NAIDU
510(k) history	1 submissions · 1 cleared · 2008-2008

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