

K130635 SEVIIN SURFACE REPLACEMENT SHOULDERAug 26, 2013
168 days to decisionK130635 · Product code: **HSD** · Orthopedic
Source: <https://www.510kdatabase.net/k130635/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented (HSD)
Date received	Mar 11, 2013
Decision date	Aug 26, 2013
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ingen Orthopedics, LLC
Location	Cranbury, NJ, US
Contact	PERRY A GEREMAKIS
510(k) history	3 submissions · 3 cleared · 2012-2013

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