

**K131277 SEVIIN FRACTURE SHOULDER**Aug 28, 2013  
114 days to decisionK131277 · Product code: **KWS** · Orthopedic  
Source: <https://www.510kdatabase.net/k131277/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	May 6, 2013
Decision date	Aug 28, 2013
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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