

K153215 SmartBase for Arthrex Glenoid IRISFeb 19, 2016
106 days to decisionK153215 · Product code: **KWS** · Orthopedic
Source: <https://www.510kdatabase.net/k153215/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Nov 5, 2015
Decision date	Feb 19, 2016
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Custom Orthopaedic Solutions, Inc.
Location	Cleveland, OH, US
Contact	Keith Grafmeyer
510(k) history	6 submissions · 6 cleared · 2014-2017

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