

K142072 GLENOID INTELLIGENT REUSABLE INSTRUMENT SYSTEM (GLENOID IRIS)

Nov 24, 2014
124 days to decision

K142072 · Product code: **KWS** · Orthopedic
Source: <https://www.510kdatabase.net/k142072/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Jul 23, 2014
Decision date	Nov 24, 2014
Days to decision	124 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k142072/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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