

K151500 Arthrex Glenoid Intelligent Reusable Instrument System (Arthrex Glenoid IRIS)

Oct 5, 2015
123 days to decision

K151500 · Product code: **KWS** · Orthopedic
Source: <https://www.510kdatabase.net/k151500/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Jun 4, 2015
Decision date	Oct 5, 2015
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Custom Orthopaedic Solutions
Location	Cleveland, OH, US
Contact	Peter D O’Neill
510(k) history	2 submissions · 2 cleared · 2013-2015

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k151500/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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