

**K212683 GLOBAL ICON Stemless Shoulder System**Jan 19, 2022  
148 days to decisionK212683 · Product code: **PKC** · Orthopedic  
Source: <https://www.510kdatabase.net/k212683/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Total Anatomic Shoulder, Uncemented Metaphyseal Humeral Stem With No Diaphyseal Incursion, Semi-constrained (PKC)
Date received	Aug 24, 2021
Decision date	Jan 19, 2022
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

Company	<b>Depuy(Ireland)</b>
Location	Cork, IE
Contact	Kathy Harris
510(k) history	13 submissions · 13 cleared · 2010-2022

**REGULATORY CONSULTANT**

Consulting firm	<b>DePuy Orthopaedics, Inc.</b>
Contact	Megan Bernier

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

**CLINICAL EVIDENCE - NCT03168672****GLOBAL ICON Stemless Shoulder System Post Market Clinical Follow Up Study**

Status	Terminated
Enrollment	171 patients (actual)
Study sites	12 sites
Condition studied	Osteoarthritis; Post Traumatic Arthritis
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jun 18, 2024
Sponsor	DePuy Orthopaedics (Industry)

**Primary outcome**

Percentage of Participants With Overall Composite Clinical Success

**Secondary outcome**

Mean Adjusted Constant-Murley Score at Baseline, 3, 12, 24, and 60 Months Post-operative

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT03168672](https://clinicaltrials.gov/study/NCT03168672)