FDA 510(k) Premarket Notification

K220216 C-Stem AMT LE Prosthesis

CLEARED

Jul 22, 2022
177 days to decision

K220216 · Product code: **JDI** · Orthopedic
Source: https://www.510kdatabase.net/k220216/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Jan 26, 2022
Decision date	Jul 22, 2022
Days to decision	177 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Depuy Ireland UC**
Location	Ringaskiddy, IE
Contact	Sarah Matamisa
510(k) history	47 submissions · 47 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	**DePuy Orthopaedics, Inc.**
Contact	Sarah Matamisa

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