FDA 510(k) Premarket Notification

K222056 Global Modular Replacement System, Modular Replacement System, Modular Rotating Hinge Knee

CLEARED

Jan 26, 2023
198 days to decision

K222056 · Product code: **JDI** · Orthopedic
Source: https://www.510kdatabase.net/k222056/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Jul 12, 2022
Decision date	Jan 26, 2023
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Howmedica Osteonics Corp., Dba Stryker Orthopaedics**
Location	Malwah, NJ, US
Contact	Margaret Klippel
Website	https://www.stryker.com
510(k) history	31 submissions · 31 cleared · 2010-2026

Howmedica Osteonics Corp., Dba Stryker Orthopaedics is a medical device manufacturer based in Malwah, US. The company operates as part of Stryker, a global medical technology leader. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2010. 97% of submissions focus on Orthopedic devices, including joint replacement systems, knee implants, and hip components. The latest clearance in 2026 demonstrates continued regulatory activity and product innovation. Recent cleared devices include the Triathlon® Total Knee System with multi...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k222056/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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