

K222632 UHR Bipolar Implants, Restoration GAP II ImplantsOct 21, 2022
51 days to decisionK222632 · Product code: **KWL** · Orthopedic
Source: <https://www.510kdatabase.net/k222632/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal (KWL)
Date received	Aug 31, 2022
Decision date	Oct 21, 2022
Days to decision	51 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Howmedica Osteonics Corp., Db a 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., Db a 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...