

K001385 HOWMEDICA OSTEONICS RADIAL HEAD PROTHESISJul 27, 2000
86 days to decisionK001385 · Product code: **KWI** · Orthopedic
Source: <https://www.510kdatabase.net/k001385/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Elbow, Hemi-, Radial, Polymer (KWI)
Date received	May 2, 2000
Decision date	Jul 27, 2000
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Howmedica Osteonics Corp.
Location	Allendale, NJ, US
Contact	JENNIFER A DAUDELIN
510(k) history	288 submissions · 288 cleared · 1999-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k001385/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026