

**K040128 MODIFICATION TO MODULAR REPLACEMENT  
SYSTEM (MRS) HUMERAL STEMS**Mar 26, 2004  
65 days to decisionK040128 · Product code: **HSD** · Orthopedic  
Source: <https://www.510kdatabase.net/k040128/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented (HSD)
Date received	Jan 21, 2004
Decision date	Mar 26, 2004
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Howmedica Osteonics Corp.</b>
Location	Allendale, NJ, US
Contact	MARGARET F CROWE
510(k) history	288 submissions · 288 cleared · 1999-2020

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040128/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 15, 2026