

K082892 REJUVENATE MONOLITHIC HIP SYSTEMDec 29, 2008
90 days to decisionK082892 · Product code: **MEH** · Orthopedic
Source: <https://www.510kdatabase.net/k082892/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Hip, Semi-constrained, Uncemented, Metal / Polymer, Non-porous, Calcium Phosphate (MEH) |
| Date received | Sep 30, 2008 |
| Decision date | Dec 29, 2008 |
| Days to decision | 90 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Howmedica Osteonics Corp. |
| Location | Allendale, NJ, US |
| Contact | DENISE DAUGERT |
| 510(k) history | 288 submissions · 288 cleared · 1999-2020 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082892/> 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 15, 2026