

K081171 TRITANIUM ACETABULAR SHELL SYSTEMJul 22, 2008
89 days to decisionK081171 · Product code: **LPH** · Orthopedic
Source: <https://www.510kdatabase.net/k081171/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH) |
| Date received | Apr 24, 2008 |
| Decision date | Jul 22, 2008 |
| Days to decision | 89 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081171/> 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