

K980081 S-ROM ZIRCONIA CERAMIC FEMORAL HIP HEADApr 9, 1998
90 days to decisionK980081 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k980081/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO) |
| Date received | Jan 9, 1998 |
| Decision date | Apr 9, 1998 |
| Days to decision | 90 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Johnson & Johnson Professionals, Inc. |
| Location | Raynham, MA, US |
| Contact | MARY E GRAY |
| Website | https://www.jnj.com |
| 510(k) history | 206 submissions · 184 cleared · 1976-2000 |

Johnson & Johnson Professionals, Inc. is a medical device company based in Raynham, Massachusetts. The company specializes in surgical and orthopedic devices. The company has received FDA 510(k) clearances from total submissions between 1976 and 2000. Orthopedic devices and neurosurgical instruments represent core product categories. Notable cleared devices include hip and elbow prostheses, programmable valve systems, and aneurysm clips. The company is inactive and represents a historical regulatory record with no submissions in more than two decades. Explore the complete...
