

K111981 TREGOR DUAL MOBILITY ACETABULAR SYSTEMOct 12, 2012
458 days to decisionK111981 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k111981/>**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 | Jul 12, 2011 |
| Decision date | Oct 12, 2012 |
| Days to decision | 458 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Aston Medical |
| Location | Santa Barbara, CA, US |
| Contact | CATHERINE GLOSTER |
| 510(k) history | 3 submissions · 3 cleared · 2011-2014 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111981/> 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 17, 2026