

K121029 METS MODULAR DISTAL FEMURSep 19, 2012
167 days to decisionK121029 · Product code: **KRO** · Orthopedic
Source: <https://www.510kdatabase.net/k121029/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/polymer (KRO) |
| Date received | Apr 5, 2012 |
| Decision date | Sep 19, 2012 |
| Days to decision | 167 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Stanmore Implants Worldwide , Ltd. |
| Location | Washington, Dc, DC, US |
| Contact | NANCY C MACDONALD |
| 510(k) history | 8 submissions · 8 cleared · 2011-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121029/> 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 14, 2026