

K123207 PRIMALIF TM LLIF UNITARY PEEK LATERAL LUMBAR INTERBODY FUSION SYSTEM

Nov 29, 2012
48 days to decision

K123207 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k123207/>

SUBMISSION DETAILS

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received | Oct 12, 2012 |
| Decision date | Nov 29, 2012 |
| Days to decision | 48 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Osteomed LP |
| Location | Addison, TX, US |
| Contact | PIEDAD PENA |
| 510(k) history | 29 submissions · 29 cleared · 2003-2015 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k123207/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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