

K141798 SYPHER SPACER SYSTEMFeb 19, 2015
231 days to decisionK141798 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k141798/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD) |
| Date received | Jul 3, 2014 |
| Decision date | Feb 19, 2015 |
| Days to decision | 231 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Biogenix, LLC |
| Location | Irvine, CA, US |
| Contact | MEREDITH MAY, MS, RAC |
| 510(k) history | 8 submissions · 8 cleared · 2010-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k141798/> 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 27, 2026