FDA 510(k) Premarket Notification

# K130913 GENESYS SPINE APACHE LATERAL LUMBAR INTERBODY FUSION SYSTEM

**CLEARED**

Dec 13, 2013
255 days to decision

K130913 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k130913/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received | Apr 2, 2013 |
| Decision date | Dec 13, 2013 |
| Days to decision | 255 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Genesys Spine** |
| Location | Austin, TX, US |
| Contact | WILLIAM W SOWERS |
| 510(k) history | 31 submissions · 31 cleared · 2010-2025 |