FDA 510(k) Premarket Notification

**CLEARED**

# K182987 Genesys Spine 3DP Lumbar Interbody System

Dec 12, 2019
409 days to decision

K182987 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k182987/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received | Oct 29, 2018 |
| Decision date | Dec 12, 2019 |
| Days to decision | 409 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 |