FDA 510(k) Premarket Notification

# K210890 GPS Cervical Spacers

**CLEARED**

Apr 23, 2021
29 days to decision

K210890 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k210890/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Intervertebral Fusion Device With Bone Graft, Cervical (ODP) |
| Date received | Mar 25, 2021 |
| Decision date | Apr 23, 2021 |
| Days to decision | 29 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **G Surgical, LLC** |
| Location | Boulder, CO, US |
| Contact | Donald Grafton |
| 510(k) history | 7 submissions · 7 cleared · 2015-2024 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Backroads Consulting** |
| Contact | Karen E. Warden |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov