FDA 510(k) Premarket Notification

**CLEARED**

# K252737 DeGen Medical Latitude-C AM Cervical Interbody Fusion System

Oct 10, 2025
43 days to decision

K252737 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k252737/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Bone Graft, Cervical (ODP) |
| Date received | Aug 28, 2025 |
| Decision date | Oct 10, 2025 |
| Days to decision | 43 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Degen Medical** |
| Location | Florence, SC, US |
| Contact | Craig Black |
| 510(k) history | 16 submissions · 16 cleared · 2015-2025 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Secure BioMed Evaluations** |
| Contact | Justin Gracyalny |

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