FDA 510(k) Premarket Notification

# K230329 F3D Interbody System

**CLEARED**

Jun 6, 2023
120 days to decision

K230329 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k230329/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Bone Graft, Cervical (ODP) |
| Date received | Feb 6, 2023 |
| Decision date | Jun 6, 2023 |
| Days to decision | 120 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Corelink, LLC** |
| Location | Round Rock, TX, US |
| Contact | Steven Mounts |
| 510(k) history | 35 submissions · 35 cleared · 2008-2023 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **MCRA** |
| Contact | Justin Eggleton |

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