FDA 510(k) Premarket Notification

# K112561 NUVASIVE COROENT NO-PROFILE SYSTEM

**CLEARED**

Mar 13, 2012
193 days to decision

K112561 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k112561/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD) |
| Date received | Sep 2, 2011 |
| Decision date | Mar 13, 2012 |
| Days to decision | 193 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Nuvasive, Inc.** |
| Location | San Diego, CA, US |
| Contact | Sheila Bruschi |
| Website | http://www.nuvasive.com/ |
| 510(k) history | 91 submissions · 90 cleared · 1999-2024 |

NuVasive, Inc. is a medical device company headquartered in San Diego, California. The company develops and markets surgical solutions focused on spine and orthopedic procedures. NuVasive operates globally and serves healthcare professionals and patients worldwide. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions since 1999. Orthopedic devices represent the dominant category, accounting for the majority of the company's cleared submissions. The most recent clearance was granted in 2024, demonstrating continued r...