FDA 510(k) Premarket Notification

# K120918 NUVASIVE COROENT TITANIUM SYSTEM

**CLEARED**

Jun 28, 2012
93 days to decision

K120918 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k120918/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received | Mar 27, 2012 |
| Decision date | Jun 28, 2012 |
| Days to decision | 93 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...