FDA 510(k) Premarket Notification

# K031657 STRYKER SPINE OASYS BONE SCREW

**CLEARED**

Aug 22, 2003
86 days to decision

K031657 · Product code: **MRW** · Orthopedic
Source: https://www.510kdatabase.net/k031657/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Facet Screw Spinal Device (MRW) |
| Date received | May 28, 2003 |
| Decision date | Aug 22, 2003 |
| Days to decision | 86 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Howmedica Osteonics Corp.** |
| Location | Allendale, NJ, US |
| Contact | KAREN ARIEMMA |
| 510(k) history | 288 submissions · 288 cleared · 1999-2020 |