FDA 510(k) Premarket Notification

# K990059 OSTEONICS SPINAL SYSTEM-EXPANDED INDICATIONS

**CLEARED**

Jan 28, 1999
20 days to decision

K990059 · Product code: **MNI** · Orthopedic
Source: https://www.510kdatabase.net/k990059/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Orthosis, Spinal Pedicle Fixation (MNI) |
| Date received | Jan 8, 1999 |
| Decision date | Jan 28, 1999 |
| Days to decision | 20 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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