

**K964544 OSTEONICS SPINAL SYSTEM - VARIABLE OFFSET
CONNECTOR ASSEMBLY**Feb 11, 1997
90 days to decisionK964544 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k964544/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Orthosis, Spondylolisthesis Spinal Fixation (MNH) |
| Date received | Nov 13, 1996 |
| Decision date | Feb 11, 1997 |
| Days to decision | 90 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Osteonics Corp. |
| Location | Mchenry, IL, US |
| Contact | DONNA S WILSON |
| 510(k) history | 178 submissions · 136 cleared · 1980-2000 |

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