

**K951626 SYNTHES (U.S.A.) UNIVERSAL SPINAL HOOK, ROD
AND PEDICLE/SACRAL SCREW FIXATION SYSTEM**Aug 21, 1995
136 days to decisionK951626 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k951626/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent - SN |
| Submission type | Traditional |
| Device classification | Orthosis, Spondylolisthesis Spinal Fixation (MNH) |
| Date received | Apr 7, 1995 |
| Decision date | Aug 21, 1995 |
| Days to decision | 136 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Synthes (Usa) |
| Location | Mchenry, IL, US |
| Contact | DIANE T BROWN |
| 510(k) history | 411 submissions · 394 cleared · 1977-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k951626/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026