

K003275 SYNTHES SYNMESH SPACER SYSTEMApr 23, 2001
186 days to decisionK003275 · Product code: **MQP** · Orthopedic
Source: <https://www.510kdatabase.net/k003275/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Spinal Vertebral Body Replacement Device (MQP) |
| Date received | Oct 19, 2000 |
| Decision date | Apr 23, 2001 |
| Days to decision | 186 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003275/> 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