

K111799 NUGAIT(TM) SUBTALAR IMPLANT SYSTEMAug 19, 2011
53 days to decisionK111799 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k111799/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Screw, Fixation, Bone (HWC) |
| Date received | Jun 27, 2011 |
| Decision date | Aug 19, 2011 |
| Days to decision | 53 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Ascension Orthopedic |
| Location | Austin, TX, US |
| Contact | BRADLEY W STRASSER |
| 510(k) history | 7 submissions · 7 cleared · 2011-2014 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111799/> 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 17, 2026