

K092889 SYNTEC OSTEO-PLATE AND SCREW FIXATIONJun 25, 2010
277 days to decisionK092889 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k092889/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plate, Fixation, Bone (HRS) |
| Date received | Sep 21, 2009 |
| Decision date | Jun 25, 2010 |
| Days to decision | 277 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Syntec Scientific Corp. |
| Location | Taipei City, TW |
| Contact | CAROL CHANG |
| 510(k) history | 13 submissions · 13 cleared · 1998-2012 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092889/> 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 18, 2026