

**K050607 SYNTHES 1.0MM TI. CORTEX, SELF-DRILLING
SCREWS (HAND & NEURO)**Apr 11, 2005
32 days to decisionK050607 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k050607/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Mar 10, 2005
Decision date	Apr 11, 2005
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050607/>; 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