

**K963325 SYNTHES TITANIUM (TI) ALLOY HIGH TIBIAL
OSTEOTOMY (HTO) SYSTEM**

Mar 25, 1997
214 days to decision

K963325 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k963325/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Aug 23, 1996
Decision date	Mar 25, 1997
Days to decision	214 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k963325/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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