

**K081353 SYNTHES (USA) TOMOFIX MEDIAL DISTAL FEMUR
PLATES**Jul 23, 2008
70 days to decisionK081353 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k081353/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	May 14, 2008
Decision date	Jul 23, 2008
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081353/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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