

K180213 Titanium TomoFix Medial High Tibia Plate AnatomicalOct 19, 2018
267 days to decisionK180213 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k180213/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jan 25, 2018
Decision date	Oct 19, 2018
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synthes USA Products, LLC
Location	West Chester, PA, US
Contact	Stephan Jepards
510(k) history	60 submissions · 60 cleared · 2010-2022

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