

K170972 Apex Tibial Nailing SystemDec 20, 2017
261 days to decisionK170972 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k170972/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Apr 3, 2017
Decision date	Dec 20, 2017
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Orthoxel
Location	Bishopstown, IE
Contact	Aisling O'Sullivan
510(k) history	2 submissions · 2 cleared · 2017-2018

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