

K151459 Integra Total Ankle Replacement SystemAug 31, 2015
91 days to decisionK151459 · Product code: **HSN** · Orthopedic
Source: <https://www.510kdatabase.net/k151459/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Ankle, Semi-constrained, Cemented, Metal/polymer (HSN)
Date received	Jun 1, 2015
Decision date	Aug 31, 2015
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ascension Orthopedics
Location	Austin, TX, US
Contact	Frederic Testa
510(k) history	7 submissions · 7 cleared · 2014-2018

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