

K182878 Integra Salto Total Ankle SystemDec 18, 2018
64 days to decisionK182878 · Product code: **HSN** · Orthopedic
Source: <https://www.510kdatabase.net/k182878/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Ankle, Semi-constrained, Cemented, Metal/polymer (HSN)
Date received	Oct 15, 2018
Decision date	Dec 18, 2018
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Integra LifeSciences Corporation
Contact	Divya Savant

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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