

K191380 Quantum® Total Ankle ProsthesisJan 29, 2020
251 days to decisionK191380 · Product code: **HSN** · Orthopedic
Source: <https://www.510kdatabase.net/k191380/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Ankle, Semi-constrained, Cemented, Metal/polymer (HSN)
Date received	May 23, 2019
Decision date	Jan 29, 2020
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	In2bones Sas
Location	Potomac, MD, US
Contact	Morgane Grenier
510(k) history	18 submissions · 18 cleared · 2014-2024

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