

**K211883 QUANTUM® Patient Specific Instrumentation (PSI)
System**Aug 11, 2021
51 days to decisionK211883 · Product code: **HSN** · Orthopedic
Source: <https://www.510kdatabase.net/k211883/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Ankle, Semi-constrained, Cemented, Metal/polymer (HSN)
Date received	Jun 21, 2021
Decision date	Aug 11, 2021
Days to decision	51 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	In2bones USA
Contact	Christine Scifert

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211883/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026