

**K231699 QUANTUM® Patient Specific Instrumentation (PSI)
System**Apr 23, 2024
316 days to decisionK231699 · Product code: **HSN** · Orthopedic
Source: <https://www.510kdatabase.net/k231699/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Ankle, Semi-constrained, Cemented, Metal/polymer (HSN)
Date received	Jun 12, 2023
Decision date	Apr 23, 2024
Days to decision	316 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	In2bones Sas
Location	Potomac, MD, US
Contact	Stephan Epinette
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/k231699/> 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 13, 2026