FDA 510(k) Premarket Notification

CLEARED

K211883 QUANTUM® Patient Specific Instrumentation (PSI) System

Aug 11, 2021
51 days to decision

K211883 · 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