FDA 510(k) Premarket Notification

CLEARED

K232265 BLUEPRINT™ Patient Specific Instrumentation

Feb 21, 2024
205 days to decision

K232265 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k232265/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Jul 31, 2023
Decision date	Feb 21, 2024
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tornier S.A.S.**
Location	Bloomington, MN, US
Contact	Aymen Azaiez
510(k) history	20 submissions · 19 cleared · 2013-2024