FDA 510(k) Premarket Notification

K162800 BLUEPRINT Patient Specific Instrumentation

CLEARED

Feb 22, 2017
140 days to decision

K162800 · Product code: **KWS** · Orthopedic
Source: https://www.510kdatabase.net/k162800/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Oct 5, 2016
Decision date	Feb 22, 2017
Days to decision	140 days
Third-party review	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