

K190521 Aequalis Ascend Flex Shoulder SystemJun 12, 2019
100 days to decisionK190521 · Product code: **KWS** · Orthopedic
Source: <https://www.510kdatabase.net/k190521/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Mar 4, 2019
Decision date	Jun 12, 2019
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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