

K181420 Aequalis Flex Revive Shoulder SystemSep 20, 2018
112 days to decisionK181420 · Product code: **KWS** · Orthopedic
Source: <https://www.510kdatabase.net/k181420/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	May 31, 2018
Decision date	Sep 20, 2018
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tornier, Inc.
Location	Beverly, MA, US
Contact	Laurie Lewandowski
510(k) history	51 submissions · 51 cleared · 2000-2026

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