

K180582 Sternal Cable SystemMay 31, 2018
87 days to decisionK180582 · Product code: **JDQ** · Orthopedic
Source: <https://www.510kdatabase.net/k180582/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cerclage, Fixation (JDQ)
Date received	Mar 5, 2018
Decision date	May 31, 2018
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	A & E Medical Corporation
Location	Farmingdale, NJ, US
Contact	Hollie Johnson
510(k) history	4 submissions · 4 cleared · 2018-2020

REGULATORY CONSULTANT

Consulting firm	Rti Surgical, Inc.
Contact	Sarah Pleaugh

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180582/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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