

**K193468 Tritium Sternal Cable Plate System**Mar 12, 2020  
87 days to decisionK193468 · Product code: **JDQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k193468/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cerclage, Fixation (JDQ)
Date received	Dec 16, 2019
Decision date	Mar 12, 2020
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pioneer Surgical Technology, Inc. (Dba Rti Surgical, Inc.)</b>
Location	Marquette, MI, US
Contact	Linda Busklein
510(k) history	15 submissions · 15 cleared · 2015-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>A &amp; E Medical Corporation</b>
Contact	Peter Browne

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

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