

K170830 Unison-C Anterior Cervical Fixation SystemJun 28, 2017
100 days to decisionK170830 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k170830/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Mar 20, 2017
Decision date	Jun 28, 2017
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pioneer Surgical Technology, Inc. (Dba Rti Surgical, Inc.)
Location	Marquette, MI, US
Contact	Sarah Pleaugh
510(k) history	15 submissions · 15 cleared · 2015-2020

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