

K152793 Unison-C Anterior Cervical Fixation SystemJan 19, 2016
113 days to decisionK152793 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k152793/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Sep 28, 2015
Decision date	Jan 19, 2016
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pioneer Surgical Technology, Inc. (Db a Rti Surgical, Inc.)
Location	Marquette, MI, US
Contact	EMILY ROBERGE
510(k) history	15 submissions · 15 cleared · 2015-2020

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