

K153250 Renovis Tesera SC Stand-alone Anterior Cervical Fusion (ACF) SystemMar 16, 2016
128 days to decisionK153250 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k153250/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Nov 9, 2015
Decision date	Mar 16, 2016
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Renovis Surgical Technologies
Location	Redlands, CA, US
Contact	ANTHONY DEBENEDICTIS
510(k) history	7 submissions · 7 cleared · 2015-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153250/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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