

K202065 DOLOMITE Anterior Cervical Stabilization SystemOct 26, 2020
91 days to decisionK202065 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k202065/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Jul 27, 2020
Decision date	Oct 26, 2020
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Astura Medical, LLC
Location	Carlsbad, CA, US
Contact	Parker Kelch
510(k) history	8 submissions · 8 cleared · 2018-2021

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