

K191477 AEON-C Stand Alone SystemNov 13, 2019
162 days to decisionK191477 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k191477/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Jun 4, 2019
Decision date	Nov 13, 2019
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Huvexel Co. , Ltd.
Location	Seongnam-Si, KR
Contact	Sung Kyu Hur
510(k) history	8 submissions · 8 cleared · 2017-2022

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