

K160313 Xenco Medical Cervical Interbody SystemOct 21, 2016
259 days to decisionK160313 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k160313/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Feb 5, 2016
Decision date	Oct 21, 2016
Days to decision	259 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Xenco Medical, LLC
Location	San Diego, CA, US
Contact	GUSTAVO PRADO
510(k) history	16 submissions · 16 cleared · 2014-2025

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