

K213456 Xenco Medical Multilevel CerviKitDec 21, 2021
56 days to decisionK213456 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k213456/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Oct 26, 2021
Decision date	Dec 21, 2021
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Secure BioMed Evaluations
Contact	Linda Braddon

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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