FDA 510(k) Premarket Notification

CLEARED

K243673 Xenco Medical CancelleX Cervical Interbody System

Jan 29, 2025
63 days to decision

K243673 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k243673/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Nov 27, 2024
Decision date	Jan 29, 2025
Days to decision	63 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	**Watershed Idea Foundry, Inc. (Dba Spitrex 3D)**
Contact	Jeffrey Brittan

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