

**K243673 Xenco Medical Canceled Cervical Interbody System**Jan 29, 2025  
63 days to decisionK243673 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k243673/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Watershed Idea Foundry, Inc. (Db a Spitrex 3D)</b>
Contact	Jeffrey Brittan

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

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