

**K243915 FIX-C 3D Ti ACIF System**Feb 18, 2025  
60 days to decisionK243915 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k243915/>**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	Dec 20, 2024
Decision date	Feb 18, 2025
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jeil Medical Corporation</b>
Location	Deer Field, IL, US
Contact	Jinwoo Kim
510(k) history	53 submissions · 53 cleared · 2002-2026

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