

**K212792 Medynus IVA (ACIF, DLIF, PLIF, TLIF, ALIF) PEEK  
Cage**Sep 23, 2021  
22 days to decisionK212792 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k212792/>**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	Sep 1, 2021
Decision date	Sep 23, 2021
Days to decision	22 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medynus, Inc.</b>
Location	Irvine, CA, US
Contact	David Shin
510(k) history	3 submissions · 3 cleared · 2021-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Eerkie Corporation</b>
Contact	Jeena Mathai

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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