

**K242457 EARP Interbody System**Oct 7, 2024  
49 days to decisionK242457 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k242457/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 19, 2024
Decision date	Oct 7, 2024
Days to decision	49 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Retropsoas Technologies, LLC</b>
Location	Frontenac, MO, US
Contact	Nicholas Poulos
510(k) history	2 submissions · 2 cleared · 2024-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Spitrex 3D (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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242457/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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