FDA 510(k) Premarket Notification

K242457 EARP Interbody System

CLEARED

Oct 7, 2024
49 days to decision

K242457 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k242457/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Spitrex 3D (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