FDA 510(k) Premarket Notification

CLEARED

K253583 LUX Expandable Lumbar Interbody System

Feb 23, 2026
98 days to decision

K253583 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k253583/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 17, 2025
Decision date	Feb 23, 2026
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Xenix Medical**
Location	Orlando, CA, US
Contact	Teresa Cherry
510(k) history	1 submissions · 1 cleared · 2026-2026