FDA 510(k) Premarket Notification

CLEARED

K223474 PathLoc-TA Expandable Lumbar Cage System

Jan 13, 2023
56 days to decision

K223474 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k223474/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 18, 2022
Decision date	Jan 13, 2023
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**L & K Biomed Co., Ltd.**
Location	Yongin-Si, KR
Contact	Katherine Kim
Website	https://www.lkbiomed.com
510(k) history	54 submissions · 54 cleared · 2010-2026