FDA 510(k) Premarket Notification

K190708 AccelFix Lumbar Interbody Fusion Cage System

CLEARED

Sep 16, 2019
181 days to decision

K190708 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k190708/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 19, 2019
Decision date	Sep 16, 2019
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k190708/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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