FDA 510(k) Premarket Notification

K193203 MOJAVE Expandable Interbody System

CLEARED

Feb 18, 2020
90 days to decision

K193203 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k193203/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 20, 2019
Decision date	Feb 18, 2020
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**K2m, Inc.**
Location	Leesburg, VA, US
Contact	Oonagh Lahiff
510(k) history	100 submissions · 97 cleared · 2007-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k193203/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026