FDA 510(k) Premarket Notification

K203014 EndoLIF Delta-Cage and DoubleWedge-Cage

CLEARED

Sep 1, 2021
335 days to decision

K203014 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k203014/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 1, 2020
Decision date	Sep 1, 2021
Days to decision	335 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Joimax GmbH**
Location	Los Gatos, CA, US
Contact	Gary Mocnik
510(k) history	7 submissions · 7 cleared · 2005-2021

REGULATORY CONSULTANT

Consulting firm	**Gary Mocnik and Associates**
Contact	Gary Mocnik

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k203014/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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