FDA 510(k) Premarket Notification

K183239 CoreLink F3D™ Lateral System

CLEARED

Dec 19, 2018
29 days to decision

K183239 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k183239/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 20, 2018
Decision date	Dec 19, 2018
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Corelink, LLC**
Location	Round Rock, TX, US
Contact	Steven Mounts
510(k) history	35 submissions · 35 cleared · 2008-2023

REGULATORY CONSULTANT

Consulting firm	**Musculoskeletal Clinical Regulatory Advisers, LLC**
Contact	Justin Eggleton

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/k183239/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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