FDA 510(k) Premarket Notification

K180814 CoreLink® M3™ Stand-Alone Anterior Lumbar System

CLEARED

Aug 10, 2018
134 days to decision

K180814 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k180814/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Mar 29, 2018
Decision date	Aug 10, 2018
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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