FDA 510(k) Premarket Notification

CLEARED

K163506 Coalesce™ (-Straight, -Convex, -Crescent, -Lateral, -Anterior, or -Oblique) Lumbar Interbody Fusion System

Jun 19, 2017
187 days to decision

K163506 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k163506/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 14, 2016
Decision date	Jun 19, 2017
Days to decision	187 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vertera, Inc.**
Location	Atlanta, GA, US
Contact	Wei Allen Chang
510(k) history	2 submissions · 2 cleared · 2015-2017