FDA 510(k) Premarket Notification

CLEARED

K182007 Renovis Tesera C/Tesera SC Anterior Cervical Fusion (ACF) System

Dec 7, 2018
133 days to decision

K182007 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k182007/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Jul 27, 2018
Decision date	Dec 7, 2018
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Renovis Surgical Technologies**
Location	Redlands, CA, US
Contact	Anthony DeBenedictis
510(k) history	7 submissions · 7 cleared · 2015-2019

REGULATORY CONSULTANT

Consulting firm	**MEDIcept, Inc.**
Contact	Sharyn Orton

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