

K181655 Renovis S180 Lateral Lumbar Interbody Fusion SystemSep 11, 2018
81 days to decisionK181655 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k181655/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 22, 2018
Decision date	Sep 11, 2018
Days to decision	81 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	MEDlcept, Inc.
Contact	Sharyn Orton

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

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