

K190398 Republic Spine Restore Intervertebral Body Fusion SystemSep 12, 2019
205 days to decisionK190398 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k190398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 19, 2019
Decision date	Sep 12, 2019
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Republic Spine, LLC
Location	Pompano Beach, FL, US
Contact	James Doulgeris
510(k) history	7 submissions · 7 cleared · 2015-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190398/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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