

**K192208 CORNICE Cervical Spacer System**Oct 9, 2019  
56 days to decisionK192208 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k192208/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Aug 14, 2019
Decision date	Oct 9, 2019
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Legend Spine Technologies</b>
Location	Bethlehem, PA, US
Contact	Steve Marinelli
510(k) history	2 submissions · 2 cleared · 2018-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mrc-X, LLC</b>
Contact	Christine Scifert

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192208/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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