

K183397 ChoiceSpine Stealth Cervical Spacer SystemMar 6, 2019
89 days to decisionK183397 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k183397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Dec 7, 2018
Decision date	Mar 6, 2019
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Choicespine, LP
Location	Chesterland, OH, US
Contact	Kim Finch
510(k) history	22 submissions · 22 cleared · 2008-2019

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