

K180401 TiWAVE-C™ Porous Titanium Cervical CageJun 14, 2018
120 days to decisionK180401 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k180401/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Feb 14, 2018
Decision date	Jun 14, 2018
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kalitec Direct, LLC
Location	Round Rock, TX, US
Contact	Scott Winn
510(k) history	9 submissions · 9 cleared · 2011-2018

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