

K170342 Ocata Anterior Cervical SystemMay 9, 2017
95 days to decisionK170342 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k170342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Feb 3, 2017
Decision date	May 9, 2017
Days to decision	95 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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