

K161334 RASL Repair KitFeb 9, 2017
273 days to decisionK161334 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k161334/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	May 12, 2016
Decision date	Feb 9, 2017
Days to decision	273 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Radicle Orthopaedics, Inc.
Location	New York, NY, US
Contact	EDWARD ROSENWASSER
510(k) history	1 submissions · 1 cleared · 2017-2017

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