

K182971 SpaceOAR Vue HydrogelJul 19, 2019
266 days to decisionK182971 · Product code: **OVB** · Radiology
Source: <https://www.510kdatabase.net/k182971/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hydrogel Spacer (OVB)
Date received	Oct 26, 2018
Decision date	Jul 19, 2019
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Augmenix, Inc.
Location	Waltham, MA, US
Contact	Marcus Garcia
510(k) history	5 submissions · 4 cleared · 2013-2019

REGULATORY CONSULTANT

Consulting firm	Boston Scientific
Contact	Marcus Garcia

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

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