

**K181465 SpaceOAR System**Jun 25, 2018  
21 days to decisionK181465 · Product code: **OVB** · Radiology  
Source: <https://www.510kdatabase.net/k181465/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hydrogel Spacer (OVB)
Date received	Jun 4, 2018
Decision date	Jun 25, 2018
Days to decision	21 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181465/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 18, 2026