

**K192371 BioZorb SP Marker**Sep 26, 2019  
27 days to decisionK192371 · Product code: **NEU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192371/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Aug 30, 2019
Decision date	Sep 26, 2019
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Focal Therapeutics</b>
Location	Portola Valley, CA, US
Contact	Dhaval Saraiya
510(k) history	5 submissions · 5 cleared · 2012-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192371/> 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 28, 2026