

K171467 BioZorb Marker GOLD / LP Marker GOLDNov 9, 2017
175 days to decisionK171467 · Product code: IYE · Radiology
Source: <https://www.510kdatabase.net/k171467/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	May 18, 2017
Decision date	Nov 9, 2017
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Focal Therapeutics
Location	Portola Valley, CA, US
Contact	George Hermann
510(k) history	5 submissions · 5 cleared · 2012-2019

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