

K143484 BioZorb MarkerJun 29, 2015
203 days to decisionK143484 · Product code: **NEU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k143484/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Dec 8, 2014
Decision date	Jun 29, 2015
Days to decision	203 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143484/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026