

**K113202 TISSUE MARKER**Feb 28, 2012  
120 days to decisionK113202 · Product code: **NEU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k113202/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Oct 31, 2011
Decision date	Feb 28, 2012
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Focal Therapeutics</b>
Location	Portola Valley, CA, US
Contact	GEORGE HERMANN
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/k113202/> 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