

**K182082 Tumark for Eviva, Tumark for Brevera**Oct 31, 2018  
90 days to decisionK182082 · Product code: **NEU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k182082/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Aug 2, 2018
Decision date	Oct 31, 2018
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Somatex Medical Technologies GmbH</b>
Location	Cambridge, MA, US
Contact	Burkhard Jakob
510(k) history	7 submissions · 7 cleared · 2008-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182082/> 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 May 27, 2026