

**K100994 PRELOADED TISSUE MARKER DEVICE**Apr 30, 2010  
21 days to decisionK100994 · Product code: **NEU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k100994/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Apr 9, 2010
Decision date	Apr 30, 2010
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Carbon Medical Technologies, Inc.</b>
Location	St, Paul, MN, US
Contact	TINA M WITTCHOW
510(k) history	16 submissions · 16 cleared · 2002-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100994/> 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 26, 2026