

**K140835 GENERAL AND PLASTIC SURGERY**May 20, 2014  
48 days to decisionK140835 · Product code: **NEU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k140835/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Apr 2, 2014
Decision date	May 20, 2014
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Scion Medical Technologies, LLC</b>
Location	Sauk Centre, MN, US
Contact	CHRIS LEWIS
510(k) history	6 submissions · 6 cleared · 2013-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140835/> 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 1, 2026