

K170905 Star Tissue MarkerApr 27, 2017
30 days to decisionK170905 · Product code: **NEU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k170905/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Mar 28, 2017
Decision date	Apr 27, 2017
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Scion Medical Technologies, LLC
Location	Sauk Centre, MN, US
Contact	Louis Li
510(k) history	6 submissions · 6 cleared · 2013-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170905/> 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 1, 2026