

**K203550 ActivSight Intraoperative Imaging System**Apr 8, 2021  
125 days to decisionK203550 · Product code: **OWN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k203550/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	Dec 4, 2020
Decision date	Apr 8, 2021
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Activ Surgical, Inc.</b>
Location	Boston, MA, US
Contact	Matthew King
510(k) history	2 submissions · 2 cleared · 2021-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203550/> 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