

**K223682 Sirius Pintuition Seed, Sirius Pintuition Probe, Sirius Pintuition Base Unit**Nov 9, 2023  
336 days to decisionK223682 · Product code: **PBY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k223682/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Temporary Tissue Marker (PBY)
Date received	Dec 8, 2022
Decision date	Nov 9, 2023
Days to decision	336 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sirius Medical Systems B.V.</b>
Location	Eindhoven, NL
Contact	Bram Schermers
510(k) history	3 submissions · 3 cleared · 2021-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223682/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026