

K200734 Sirius Pintuition Seed, Sirius Pintuition Probe, Sirius Pintuition Base UnitFeb 24, 2021
341 days to decisionK200734 · Product code: **PBY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k200734/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Temporary Tissue Marker (PBY)
Date received	Mar 20, 2020
Decision date	Feb 24, 2021
Days to decision	341 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200734/>. 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 May 26, 2026