

K222643 Sirius Pintuition Seed, Sirius Pintuition Probe, Sirius Pintuition Base UnitOct 19, 2022
48 days to decisionK222643 · Product code: **PBY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k222643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Temporary Tissue Marker (PBY)
Date received	Sep 1, 2022
Decision date	Oct 19, 2022
Days to decision	48 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

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