

K251957 Coaptium Connect with Tissium Light

Sep 8, 2025
75 days to decision

K251957 · Product code: **SFD** · Neurology
Source: <https://www.510kdatabase.net/k251957/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	In Situ Polymerizing Peripheral Nerve Repair Device (SFD)
Date received	Jun 25, 2025
Decision date	Sep 8, 2025
Days to decision	75 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tissium SA
Location	Paris, FR
Contact	Bahija Ikched
510(k) history	2 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k251957/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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