

**K201931 Dixi Medical Intraoperative Subdural Electrodes  
(Strips and Grids)**Oct 2, 2021  
446 days to decisionK201931 · Product code: **GYC** · Neurology  
Source: <https://www.510kdatabase.net/k201931/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cortical (GYC)
Date received	Jul 13, 2020
Decision date	Oct 2, 2021
Days to decision	446 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dixi Medical</b>
Location	Chaufontaine, FR
Contact	Lucie Petegnief
510(k) history	3 submissions · 3 cleared · 2017-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Domecus Consulting Services, LLC</b>
Contact	Cindy Domecus

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201931/> 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 24, 2026