

**K202087 DIXI Medical Microdeep Micro-Macro Depth Electrodes**Nov 18, 2021  
478 days to decisionK202087 · Product code: **GZL** · Neurology  
Source: <https://www.510kdatabase.net/k202087/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Depth (GZL)
Date received	Jul 28, 2020
Decision date	Nov 18, 2021
Days to decision	478 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	Steve Plymale

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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