

K211954 Subdural Electrode, Strip/Intraoperative Strip, Grid/Intraoperative Grid, Multi-Strip and Split Grid, Intraoperative Mapping GridNov 10, 2022
505 days to decisionK211954 · Product code: **GYC** · Neurology
Source: <https://www.510kdatabase.net/k211954/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cortical (GYC)
Date received	Jun 23, 2021
Decision date	Nov 10, 2022
Days to decision	505 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spes Medica Srl
Location	Battipaglia, IT
Contact	Giorgio Facco
510(k) history	9 submissions · 9 cleared · 2009-2022

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