

K961942 EPIDURAL PEG ELECTRODE (EP), SPHENOIDAL ELECTRODE (EDS) AND FORAMEN, OVALE DEPTH ELECTRODE (ED-FO) FOR EPILEPSY MONITORI

Aug 18, 1997
455 days to decision

K961942 · Product code: **GYC** · Neurology
Source: <https://www.510kdatabase.net/k961942/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cortical (GYC)
Date received	May 20, 1996
Decision date	Aug 18, 1997
Days to decision	455 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Radionics, Inc.
Location	Walker, MI, US
Contact	AMY J LAFORTE
510(k) history	56 submissions · 56 cleared · 1982-2003

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Device record: <https://www.510kdatabase.net/k961942/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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