

**K041285 GYRUS G3 SYSTEM (GENERATOR, ASSESSORIES,
SOMNOPLASTY ELECTRODES AND PLASMACION
ELECTRODES)**Sep 10, 2004
120 days to decisionK041285 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k041285/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	May 13, 2004
Decision date	Sep 10, 2004
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gyrus Medical , Ltd.
Location	England, GB
Contact	ANDREW DZIMITROWICZ
510(k) history	8 submissions · 8 cleared · 1990-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k041285/> Data sourced from FDA 510(k) public records (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. - Generated June 29, 2026