

K192265 gi-4000 Electrosurgical GeneratorMay 21, 2020
274 days to decisionK192265 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192265/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 21, 2019
Decision date	May 21, 2020
Days to decision	274 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	United States Endoscopy Group, Inc.
Location	Mentor, OH, US
Contact	Carroll L. Martin
510(k) history	94 submissions · 92 cleared · 1991-2020

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