

**K100816 PK SUPERPULSE SYSEM GENERATOR MODEL
744000**Jul 1, 2010
100 days to decisionK100816 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k100816/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Mar 23, 2010
Decision date	Jul 1, 2010
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gyrus Acmi, Inc.
Location	Westborough, MA, US
Contact	GRAHAM A.L. BAILLIE
Website	https://www.olympusmedical.com
510(k) history	42 submissions · 42 cleared · 2007-2026

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