

**K080093 PKS PLASMA MORCELLATOR, MODELS 962000PK,
3620PK**May 2, 2008
109 days to decisionK080093 · Product code: **GEI** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k080093/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jan 14, 2008
Decision date	May 2, 2008
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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