

K081766 PKS OMNI INSTRUMENTAug 8, 2008
49 days to decisionK081766 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k081766/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 20, 2008
Decision date	Aug 8, 2008
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gyrus-Acmi L.P.
Location	Southborough, MA, US
Contact	LORRAINE CALZETTA
510(k) history	1 submissions · 1 cleared · 2008-2008

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