

K142154 PK NEEDLEDec 19, 2014
135 days to decisionK142154 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k142154/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 6, 2014
Decision date	Dec 19, 2014
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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