

K120567 GYRUS AMCI PK BUTTON ELECTRODEJun 20, 2012
114 days to decisionK120567 · Product code: **FAS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k120567/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrosurgical, Active, Urological (FAS)
Date received	Feb 27, 2012
Decision date	Jun 20, 2012
Days to decision	114 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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