

K093181 GYRUS ACMI PK BUTTON ELECTRODEFeb 24, 2010
139 days to decisionK093181 · Product code: **FAS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k093181/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrosurgical, Active, Urological (FAS)
Date received	Oct 8, 2009
Decision date	Feb 24, 2010
Days to decision	139 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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