

K111059 GYRUS ACMIL BIPOLAR LAPROSCOPIC LOOP (PKS BILL)Sep 1, 2011
136 days to decisionK111059 · Product code: **HIN** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k111059/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coagulator-cutter, Endoscopic, Bipolar (and Accessories) (HIN)
Date received	Apr 18, 2011
Decision date	Sep 1, 2011
Days to decision	136 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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