

K122605 PKS BILLDec 5, 2012
100 days to decisionK122605 · Product code: **HIN** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k122605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Coagulator-cutter, Endoscopic, Bipolar (and Accessories) (HIN)
Date received	Aug 27, 2012
Decision date	Dec 5, 2012
Days to decision	100 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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