

K092571 GYRUS ACMI BIOCOAG PROBEOct 20, 2010
425 days to decisionK092571 · Product code: **KNS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k092571/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Aug 21, 2009
Decision date	Oct 20, 2010
Days to decision	425 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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