

**K092278 GYRUS ACMI INVISIO DIGITAL HYSTEROSCOPE,
MODEL IDH-4**Sep 29, 2009
63 days to decisionK092278 · Product code: **HIH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k092278/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Jul 28, 2009
Decision date	Sep 29, 2009
Days to decision	63 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092278/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 22, 2026