

K875314 GL-35 COLPOSCOPIC LASER SYSTEMAug 5, 1988
220 days to decisionK875314 · Product code: **HHR** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k875314/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Surgical, Gynecologic (HHR)
Date received	Dec 29, 1987
Decision date	Aug 5, 1988
Days to decision	220 days
Third-party review	No

APPLICANT

Company	Laser Engineering, Inc.
Location	Milford, MA, US
Contact	ROBERT I RUDKO
510(k) history	18 submissions · 18 cleared · 1988-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k875314/>; 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 May 26, 2026