

**K861845 MODEL 8-B WITH LA-2B ATTACHMENT FOR OB-GYN  
USE**Aug 11, 1986  
90 days to decisionK861845 · Product code: **HHR** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k861845/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Surgical, Gynecologic (HHR)
Date received	May 13, 1986
Decision date	Aug 11, 1986
Days to decision	90 days
Third-party review	No

**APPLICANT**

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Company	<b>Directed Energy, Inc.</b>
Location	Walker, MI, US
Contact	EDWARD JOHANSEN
510(k) history	39 submissions · 38 cleared · 1984-1991

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k861845/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 22, 2026