

**K881735 CONDOM**Jul 5, 1988  
74 days to decisionK881735 · Product code: **HIS** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k881735/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Apr 22, 1988
Decision date	Jul 5, 1988
Days to decision	74 days
Third-party review	No

**APPLICANT**

---

Company	<b>Iris Medical Ent., Inc.</b>
Location	Washington, DC, US
Contact	LESLIE KUX
510(k) history	1 submissions · 1 cleared · 1988-1988

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k881735/>; 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 June 30, 2026