

**K772218 CATHETER, SILICONE COATED**Dec 13, 1977  
11 days to decisionK772218 · Product code: **EZL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k772218/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Dec 2, 1977
Decision date	Dec 13, 1977
Days to decision	11 days
Third-party review	No

**APPLICANT**

---

Company	<b>Concord Laboratories, Inc.</b>
Location	Mchenry, IL, US
Website	<a href="https://www.concordlabs.com">https://www.concordlabs.com</a>
510(k) history	42 submissions · 38 cleared · 1976-1989

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k772218/>; 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 27, 2026