

**K852324 URETERAL DILATOR**Aug 21, 1985  
83 days to decisionK852324 · Product code: **EZN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k852324/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	May 30, 1985
Decision date	Aug 21, 1985
Days to decision	83 days
Third-party review	No

**APPLICANT**

---

Company	<b>American Edwards Laboratories</b>
Location	Walker, MI, US
Contact	RONALD J EHMSEN
510(k) history	89 submissions · 88 cleared · 1980-1987

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k852324/>; 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 14, 2026