

**K842206 DIAFLEX NEPHROSTOMY BALLOON DILATOR**Oct 2, 1984  
120 days to decisionK842206 · Product code: **EZN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k842206/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Jun 4, 1984
Decision date	Oct 2, 1984
Days to decision	120 days
Third-party review	No

**APPLICANT**

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

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