

**K961697 OPTICON FEMALE URINARY INCONTINENCE  
CATHETER FOR CONTINUOUS DRAINAGE**Aug 30, 1996  
120 days to decisionK961697 · Product code: **EZL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k961697/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	May 2, 1996
Decision date	Aug 30, 1996
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medical Device Intl., Inc.</b>
Location	Minnetonka, MN, US
Contact	GREG SACHS
510(k) history	1 submissions · 1 cleared · 1996-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k961697/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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