

K970716 OPTICON DIRECT MALE URINARY CATHETER FOR CONTINUOUS DRAINAGEMay 16, 1997
78 days to decisionK970716 · Product code: **EZL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k970716/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Feb 27, 1997
Decision date	May 16, 1997
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Opticon Medical, Inc.
Location	Gurnee, IL, US
Contact	GREG SACHS
510(k) history	7 submissions · 7 cleared · 1990-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970716/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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