

**K982626 URETHROPEXY SUTURE PLACEMENT KIT MODEL
NUMBERS UM-300, MW-100, MINI-LAPAROTOMY MMK KIT
MODEL UM-250, LAPAROSCOPIC BURCH0**

Aug 20, 1998
23 days to decision

K982626 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k982626/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Jul 28, 1998
Decision date	Aug 20, 1998
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medworks Corp.
Location	Pawtucket, RI, US
Contact	PAMELA PAPINEAU
510(k) history	3 submissions · 3 cleared · 1998-1999

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Device record: <https://www.510kdatabase.net/k982626/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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