

**K971796 LAPAROTOMY BLADDER NECK SUSPENSION KIT
WITH BONE ANCHORS**

Aug 12, 1997
89 days to decision

K971796 · Product code: **EZL** · Orthopedic
Source: <https://www.510kdatabase.net/k971796/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	May 15, 1997
Decision date	Aug 12, 1997
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Louisville Laboratories, Inc.
Location	Weston, MA, US
Contact	MARY MCNAMARA-CULLINANE
510(k) history	12 submissions · 12 cleared · 1989-1998

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Device record: <https://www.510kdatabase.net/k971796/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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