

**K030813 PRIMARY CARE SOLUTIONS PREFILLED 10CC AND
PREFILLED 30CC INFLATION SYRINGES WITH STERILE
WATER CATALOG NUMBERS 1010 AND**May 30, 2003
77 days to decisionK030813 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k030813/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Mar 14, 2003
Decision date	May 30, 2003
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Primary Care Solutions, Inc.
Location	Ringwood, NJ, US
Contact	RON MADDIX
510(k) history	4 submissions · 4 cleared · 2001-2008

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