

**K031748 VITALCARE STERILEWATER AND 0.9% SODIUM CHLORIDE PRE-FILLED 10CC/30CC SYRINGES**Aug 27, 2003  
83 days to decisionK031748 · Product code: **EZL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k031748/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Jun 5, 2003
Decision date	Aug 27, 2003
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vitalcare Group, Inc.</b>
Location	Miami, FL, US
Contact	MICHAEL MCAVENIA
510(k) history	8 submissions · 8 cleared · 1998-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031748/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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