

**K070048 GUARDIAN CATHETER-INFANT URINARY  
COLLECTION KIT**Mar 15, 2007  
71 days to decisionK070048 · Product code: **FCM** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k070048/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tray, Catheterization, Sterile Urethral, With Or Without Catheter (kit) (FCM)
Date received	Jan 3, 2007
Decision date	Mar 15, 2007
Days to decision	71 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Marian Medical, Inc.</b>
Location	Destin, FL, US
Contact	SANDRA WINKLER
510(k) history	4 submissions · 4 cleared · 2005-2007

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