

**K102616 NAVIAID BALLOON GUIDED COLONOSCOPY (BGC)  
DEVICE**Dec 30, 2010  
111 days to decisionK102616 · Product code: **FDF** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k102616/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Sep 10, 2010
Decision date	Dec 30, 2010
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Smart Medical Systems , Ltd.</b>
Location	Kfar Saba, IL
Contact	ADVA YOSELZON
510(k) history	9 submissions · 9 cleared · 2006-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k102616/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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