

**K091405 PILLCAM PLATFORM WITH PILLCAM SB CAPSULES  
WITH PILLCAM SENSORBELT**Jul 29, 2009  
78 days to decisionK091405 · Product code: **NEZ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k091405/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Gastrointestinal, Wireless, Capsule (NEZ)
Date received	May 12, 2009
Decision date	Jul 29, 2009
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Given Imaging , Ltd.</b>
Location	Ra&apos;Ananna 43373, IL
Contact	Tim Thomas
Website	<a href="http://www.givenimaging.com">http://www.givenimaging.com</a>
510(k) history	30 submissions · 28 cleared · 2001-2018

Given Imaging, Ltd. specializes in capsule endoscopy and diagnostic imaging systems for Gastroenterology & Urology applications. The company operates with a manufacturing facility in Ra&apos;anana, Israel. Given Imaging received FDA 510(k) clearances from total submissions between 2001 and 2018. The company&apos;s portfolio focuses entirely on Gastroenterology & Urology devices, including capsule endoscopy platforms and diagnostic software systems. The company is currently inactive, with no clearances recorded in the past five years. Notable cleared devices include the PillCam fami...