

**K123864 GIVEN PILLCAM ENDOSCOPY SYSTEM WITH RAPID
8.0, GIVEN PILLCAM SB 3 CAPSULE ENDOSCOPY SYSTEM**Aug 12, 2013
238 days to decisionK123864 · Product code: **NEZ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k123864/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Gastrointestinal, Wireless, Capsule (NEZ)
Date received	Dec 17, 2012
Decision date	Aug 12, 2013
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Given Imaging , Ltd.
Location	Ra'Ananna 43373, IL
Contact	Tim Thomas
Website	http://www.givenimaging.com
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'anana, Israel. Given Imaging received FDA 510(k) clearances from total submissions between 2001 and 2018. The company'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...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123864/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026