

**K053639 GIVEN DIAGNOSTIC SYSTEM**May 8, 2006  
129 days to decisionK053639 · Product code: **NEZ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k053639/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Gastrointestinal, Wireless, Capsule (NEZ)
Date received	Dec 30, 2005
Decision date	May 8, 2006
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Given Imaging , Ltd.</b>
Location	Ra&apos;anana 43373, IL
Contact	SHOSHANA FRIEDMAN
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...

---