

**K071153 GIVEN DIAGNOSTIC SYSTEM WITH PILLCAM ESO2
CAPSULE**Jun 11, 2007
47 days to decisionK071153 · Product code: **NSI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k071153/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Esophageal, Wireless, Capsule (NSI)
Date received	Apr 25, 2007
Decision date	Jun 11, 2007
Days to decision	47 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Given Imaging , Ltd.
Location	Ra'anana 43373, IL
Contact	SHOSHANA FRIEDMAN
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...