

K170839 RAPID WebMay 26, 2017
66 days to decisionK170839 · Product code: **NEZ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k170839/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Gastrointestinal, Wireless, Capsule (NEZ)
Date received	Mar 21, 2017
Decision date	May 26, 2017
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Given Imaging , Ltd.
Location	Ra'anana 43373, IL
Contact	Hilla Debby
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...
