

K211684 PillCam SB 3 capsule endoscopy system, PillCam Software 9.0EAug 27, 2021
87 days to decisionK211684 · Product code: **NEZ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k211684/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Gastrointestinal, Wireless, Capsule (NEZ)
Date received	Jun 1, 2021
Decision date	Aug 27, 2021
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Given Imaging Ltd. (Medtronic)
Location	Yoqneam Northern, IL
Contact	Efrat Shamgar
510(k) history	2 submissions · 2 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
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Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211684/>; 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 25, 2026