

K230991 PillCam SB 3 capsule endoscopy system, PillCam Software 9.0EJun 30, 2023
85 days to decisionK230991 · Product code: **NEZ** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k230991/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Gastrointestinal, Wireless, Capsule (NEZ)
Date received	Apr 6, 2023
Decision date	Jun 30, 2023
Days to decision	85 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	Breanna Hessler
510(k) history	2 submissions · 2 cleared · 2021-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230991/>. 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 26, 2026