

**K240276 PillCam™ Genius SB System with PillCam Software v9.7 and PillCam Cloud Reader Software**May 10, 2024  
100 days to decisionK240276 · Product code: **NEZ** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k240276/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Gastrointestinal, Wireless, Capsule (NEZ)
Date received	Jan 31, 2024
Decision date	May 10, 2024
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Given Imaging Ltd. (D.B.A. Medtronic)</b>
Location	Yoqneam Northern, IL
Contact	Aaron Niklaus
510(k) history	1 submissions · 1 cleared · 2024-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240276/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026