

**K252617 MiroCam® Capsule Endoscope System**May 8, 2026  
262 days to decisionK252617 · Product code: **NEZ** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k252617/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Gastrointestinal, Wireless, Capsule (NEZ)
Date received	Aug 19, 2025
Decision date	May 8, 2026
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Intromedic Co., Ltd.</b>
Location	Guro-Gu , Seoul, KR
Contact	Guyeon Jung
510(k) history	11 submissions · 11 cleared · 2011-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Acts</b>
Contact	Yujung Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252617/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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