FDA 510(k) Premarket Notification

K252617 MiroCam® Capsule Endoscope System

CLEARED

May 8, 2026
262 days to decision

K252617 · Product code: **NEZ** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k252617/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Acts**
Contact	Yujung Lee

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