

K170438 MiroCam Capsule Endoscope SystemJan 30, 2018
351 days to decisionK170438 · Product code: **NEZ** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k170438/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Gastrointestinal, Wireless, Capsule (NEZ)
Date received	Feb 13, 2017
Decision date	Jan 30, 2018
Days to decision	351 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	Jinyoung Lee
510(k) history	11 submissions · 11 cleared · 2011-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170438/> 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 June 18, 2026