

K180732 MiroCam Capsule Endoscope SystemNov 8, 2018
233 days to decisionK180732 · Product code: **NEZ** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k180732/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Gastrointestinal, Wireless, Capsule (NEZ)
Date received	Mar 20, 2018
Decision date	Nov 8, 2018
Days to decision	233 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/k180732/> 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