

**K123428 MIROCAM CAPSULE ENDOSCOPE SYSTEM**May 20, 2013  
194 days to decisionK123428 · Product code: **NEZ** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k123428/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Gastrointestinal, Wireless, Capsule (NEZ)
Date received	Nov 7, 2012
Decision date	May 20, 2013
Days to decision	194 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123428/> 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 June 18, 2026