

**K134005 MIROCAM CAPSULE ENDOSCOPE SYSTEM**Jul 9, 2014  
194 days to decisionK134005 · Product code: **NEZ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k134005/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Gastrointestinal, Wireless, Capsule (NEZ)
Date received	Dec 27, 2013
Decision date	Jul 9, 2014
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	JINYOUNG LEE
510(k) history	11 submissions · 11 cleared · 2011-2026

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