

**K111450 MIROCAM CAPSULE ENDOSCOPE SYSTEM**May 18, 2012  
359 days to decisionK111450 · Product code: **NEZ** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k111450/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Traditional  |
| Device classification | System, Imaging, Gastrointestinal, Wireless, Capsule (NEZ) |
| Date received         | May 25, 2011   |
| Decision date         | May 18, 2012   |
| Days to decision      | 359 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        | JEFFREY ROBERTS                         |
| 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/k111450/> 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