

K051645 EVIS EXERA 160A SYSTEMOct 13, 2005
115 days to decisionK051645 · Product code: **NWB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k051645/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Endoscope, Accessories, Narrow Band Spectrum (NWB) |
| Date received | Jun 20, 2005 |
| Decision date | Oct 13, 2005 |
| Days to decision | 115 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Olympus Medical Systems Corporation |
| Location | Melville, NY, US |
| Contact | LAURA STORMS-TYLER |
| 510(k) history | 81 submissions · 81 cleared · 2004-2026 |

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