

**K100584 EVIS EXERAI 180 SYSTEM**Jul 2, 2010  
122 days to decisionK100584 · Product code: **NWB** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k100584/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                 |
| Submission type       | Traditional  |
| Device classification | Endoscope, Accessories, Narrow Band Spectrum (NWB) |
| Date received         | Mar 2, 2010  |
| Decision date         | Jul 2, 2010  |
| Days to decision      | 122 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

---

|                |  |
|----------------|--|
| Company        | <b>Olympus Medical Systems Corporation</b> |
| Location       | Melville, NY, US                           |
| Contact        | STACY A KLUESNER                           |
| 510(k) history | 81 submissions · 81 cleared · 2004-2026    |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100584/> 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 20, 2026