

**K051541 GF-UE160-AL5 ULTRASOUND ENDOSCOPE**Jul 1, 2005  
21 days to decisionK051541 · Product code: **FDF** · Radiology  
Source: <https://www.510kdatabase.net/k051541/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | Colonoscope And Accessories, Flexible/rigid (FDF) |
| Date received         | Jun 10, 2005                                      |
| Decision date         | Jul 1, 2005                                       |
| Days to decision      | 21 days   |
| Third-party review    | Yes   |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Olympus America, Inc.</b>              |
| Location       | Lake Success, NY, US                      |
| Contact        | LAURA STORMS-TYLER                        |
| 510(k) history | 149 submissions · 149 cleared · 1994-2012 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k051541/> 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 May 18, 2026