

**K163492 Oracle EUS Balloon**Jan 6, 2017  
24 days to decisionK163492 · Product code: **FDF** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k163492/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Special  |
| Device classification | Colonoscope And Accessories, Flexible/rigid (FDF)  |
| Date received         | Dec 13, 2016   |
| Decision date         | Jan 6, 2017  |
| Days to decision      | 24 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Statement  |
| Other names           | Oracle EUS latex balloon - Olympus Radial; Oracle EUS latex balloon - Olympus Linear; Oracle EUS latex balloon - Fujinon Radial; Oracle EUS latex balloon - Fujinon Linear |

**APPLICANT**

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|----------------|--|
| Company        | <b>United States Endoscopy Group, Inc.</b> |
| Location       | Mentor, OH, US                             |
| Contact        | Carroll Martin                             |
| 510(k) history | 94 submissions · 92 cleared · 1991-2020    |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163492/> 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 15, 2026