

**K182004 PENTAX Medical Endoscopic Ultrasound System**Aug 21, 2018  
25 days to decisionK182004 · Product code: **ODG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k182004/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                           |
| Submission type       | Special  |
| Device classification | Endoscopic Ultrasound System, Gastroenterology-urology (ODG) |
| Date received         | Jul 27, 2018   |
| Decision date         | Aug 21, 2018   |
| Days to decision      | 25 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Pentax of America, Inc.</b>          |
| Location       | West Cadwell, NJ, US                    |
| Contact        | William Goeller                         |
| 510(k) history | 44 submissions · 44 cleared · 2012-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182004/> 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 30, 2026