

K180731 Ultramatrix EUS BalloonApr 19, 2018
30 days to decisionK180731 · Product code: **ODG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k180731/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Endoscopic Ultrasound System, Gastroenterology-urology (ODG) |
| Date received | Mar 20, 2018 |
| Decision date | Apr 19, 2018 |
| Days to decision | 30 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | United States Endoscopy Group, Inc. (Us Endoscopy) |
| Location | Mentor, OH, US |
| Contact | Coletta Cohara |
| 510(k) history | 1 submissions · 1 cleared · 2018-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180731/> Data sourced from FDA 510(k) public records (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. - Generated June 15, 2026