

K122270 OVERTUBE ENDOSCOPIC ACCESS SYSTEMSep 28, 2012
60 days to decisionK122270 · Product code: **FED** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k122270/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Endoscopic Access Overtube, Gastroenterology-urology (FED) |
| Date received | Jul 30, 2012 |
| Decision date | Sep 28, 2012 |
| Days to decision | 60 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Apollo Endosurgery, Inc. |
| Location | Austin, TX, US |
| Contact | HEATHER CRAWFORD, RAC |
| 510(k) history | 12 submissions · 10 cleared · 2008-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122270/> 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 May 26, 2026