

K180292 PENTAX Video Upper G.I. Scope EG34-i10Oct 12, 2018
253 days to decisionK180292 · Product code: **FDS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k180292/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Gastroscope And Accessories, Flexible/rigid (FDS) |
| Date received | Feb 1, 2018 |
| Decision date | Oct 12, 2018 |
| Days to decision | 253 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Pentax Medical of America, Inc. |
| Location | Montvale, NJ, US |
| Contact | James W. Monroe |
| 510(k) history | 2 submissions · 2 cleared · 2018-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180292/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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