

**K131946 ENTAX ULTRASOUND VIDEO BRONCHOSCOPE
EB-1970UK + HI VISIN PREIRUS**

Apr 25, 2014
302 days to decision

K131946 · Product code: **EOQ** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k131946/>

SUBMISSION DETAILS

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Bronchoscope (flexible Or Rigid) (EOQ) |
| Date received | Jun 27, 2013 |
| Decision date | Apr 25, 2014 |
| Days to decision | 302 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Pentax Medical Company |
| Location | Montvale, NJ, US |
| Contact | KRISHNA GOVINDARAJAN |
| 510(k) history | 12 submissions · 12 cleared · 2004-2014 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k131946/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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