

K152182 Fuse Gastroscopy System

Dec 10, 2015
127 days to decision

K152182 · Product code: **FDS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k152182/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Gastroscope And Accessories, Flexible/rigid (FDS) |
| Date received | Aug 5, 2015 |
| Decision date | Dec 10, 2015 |
| Days to decision | 127 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Endochoice, Inc. |
| Location | Chalotte, NC, US |
| Contact | DANIEL HOEFER |
| 510(k) history | 27 submissions · 25 cleared · 2010-2016 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k152182/> 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 24, 2026