

K151475 EndoChoice Select Injection NeedleFeb 8, 2016
251 days to decisionK151475 · Product code: **FBK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k151475/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Endoscopic Injection Needle, Gastroenterology-urology (FBK) |
| Date received | Jun 2, 2015 |
| Decision date | Feb 8, 2016 |
| Days to decision | 251 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151475/> 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