

K060057 PROTEGE EVERFLEX SELF-EXPANDING BILIARY STENT SYSTEMMar 8, 2006
58 days to decisionK060057 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k060057/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent - U |
| Submission type | Special |
| Device classification | Stents, Drains And Dilators For The Biliary Ducts (FGE) |
| Date received | Jan 9, 2006 |
| Decision date | Mar 8, 2006 |
| Days to decision | 58 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ev3, Inc. |
| Location | Plymouth, MN, US |
| Contact | MELISSA SOMMERFELD |
| 510(k) history | 35 submissions · 26 cleared · 2003-2014 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k060057/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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