

K050501 MODIFICATION TO: XCEED NITINOL SELF-EXPANDING TRANSHEPATIC BILIARY STENT SYSTEMMar 14, 2005
14 days to decisionK050501 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k050501/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent - U |
| Submission type | Special |
| Device classification | Stents, Drains And Dilators For The Biliary Ducts (FGE) |
| Date received | Feb 28, 2005 |
| Decision date | Mar 14, 2005 |
| Days to decision | 14 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Abbott Vascular Devices |
| Location | Redwood, CA, US |
| Contact | ANN E LEONARD |
| 510(k) history | 2 submissions · 1 cleared · 2005-2005 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050501/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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