

K111627 SUPERA VERITAS(R) INTERWOVEN SELF-EXPANDING NITINOL STENT TRANSHEPATIC BILIARY SYSTEMAug 21, 2012
438 days to decisionK111627 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k111627/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent - U |
| Submission type | Traditional |
| Device classification | Stents, Drains And Dilators For The Biliary Ducts (FGE) |
| Date received | Jun 10, 2011 |
| Decision date | Aug 21, 2012 |
| Days to decision | 438 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Idev Technologies, Inc. |
| Location | Houston, TX, US |
| Contact | DARLENE GARNER |
| 510(k) history | 11 submissions · 4 cleared · 2003-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111627/> 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 June 9, 2026