

K980191 MANAN BILIARY DRAINAGE CATHETERFeb 9, 1998
20 days to decisionK980191 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k980191/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stents, Drains And Dilators For The Biliary Ducts (FGE) |
| Date received | Jan 20, 1998 |
| Decision date | Feb 9, 1998 |
| Days to decision | 20 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Medical Device Technologies, Inc. |
| Location | Gainesville, FL, US |
| Contact | KARL SWARTZ |
| 510(k) history | 46 submissions · 46 cleared · 1992-2010 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k980191/> 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 20, 2026