

K921191 GIANTURCO-ROSCH BILIARY Z STENTMay 15, 1992
78 days to decisionK921191 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k921191/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stents, Drains And Dilators For The Biliary Ducts (FGE) |
| Date received | Feb 27, 1992 |
| Decision date | May 15, 1992 |
| Days to decision | 78 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Cook, Inc. |
| Location | Mchenry, IL, US |
| Contact | APRIL LAVENDER |
| 510(k) history | 190 submissions · 179 cleared · 1976-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k921191/> 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 14, 2026