

**K953827 GIP/MEDI-GLOBE ERCP CATHETERS**Sep 1, 1995  
17 days to decisionK953827 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k953827/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                      |
| Submission type       | Traditional   |
| Device classification | Stents, Drains And Dilators For The Biliary Ducts (FGE) |
| Date received         | Aug 15, 1995  |
| Decision date         | Sep 1, 1995   |
| Days to decision      | 17 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Medi-Globe Corp.</b>                 |
| Location       | Irvine, CA, US                          |
| Contact        | GINA M GALLEGOS                         |
| 510(k) history | 18 submissions · 17 cleared · 1990-2006 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k953827/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026