

K011261 STONE EXTRACTOR BALLOON CATHETERNov 17, 2003
936 days to decisionK011261 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k011261/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stents, Drains And Dilators For The Biliary Ducts (FGE) |
| Date received | Apr 25, 2001 |
| Decision date | Nov 17, 2003 |
| Days to decision | 936 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Medi-Globe Corp. |
| Location | Irvine, CA, US |
| Contact | SCOTT KARLER |
| 510(k) history | 18 submissions · 17 cleared · 1990-2006 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011261/> 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 29, 2026