

K023090 OPTION-VF URINARY CATHETER, FV14218Mar 19, 2003
183 days to decisionK023090 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k023090/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Retention Type, Balloon (EZL) |
| Date received | Sep 17, 2002 |
| Decision date | Mar 19, 2003 |
| Days to decision | 183 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Opticon Medical, Inc. |
| Location | Gurnee, IL, US |
| Contact | GLENN D BRUNNER |
| 510(k) history | 7 submissions · 7 cleared · 1990-2004 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k023090/> 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 26, 2026