

**K944381 ORION ALL SILICONE FOLEY CATHETER
TEMPERATURE PROBE**Nov 30, 1994
84 days to decisionK944381 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k944381/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Retention Type, Balloon (EZL) |
| Date received | Sep 7, 1994 |
| Decision date | Nov 30, 1994 |
| Days to decision | 84 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|--|
| Company | Regulatory & Marketing Services, Inc. |
| Location | Palm Harbor, FL, US |
| Contact | PATRICK J LAMB |
| 510(k) history | 21 submissions · 17 cleared · 1993-1996 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944381/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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