

K071049 DOVER 100% SILICONE FOLEY CATHETER WITH TEMPERATURE SENSOR

Oct 16, 2007
186 days to decision

K071049 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k071049/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Retention Type, Balloon (EZL) |
| Date received | Apr 13, 2007 |
| Decision date | Oct 16, 2007 |
| Days to decision | 186 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Tyco Healthcare |
| Location | Mansfield, MA, US |
| Contact | WEI ZHAO |
| 510(k) history | 14 submissions · 14 cleared · 2001-2007 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k071049/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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