

K241424 InnoCare Specialty Foley CatheterSep 18, 2024
121 days to decisionK241424 · Product code: **EZL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k241424/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Retention Type, Balloon (EZL) |
| Date received | May 20, 2024 |
| Decision date | Sep 18, 2024 |
| Days to decision | 121 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Innocare Urologics, LLC |
| Location | Miami, FL, US |
| Contact | Patrick McCain |
| 510(k) history | 1 submissions · 1 cleared · 2024-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241424/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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