

K250910 Optilume® High Pressure Urological Balloon Dilation CatheterMay 22, 2025
57 days to decisionK250910 · Product code: **EZN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k250910/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dilator, Catheter, Ureteral (EZN) |
| Date received | Mar 26, 2025 |
| Decision date | May 22, 2025 |
| Days to decision | 57 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Urotronic, Inc. |
| Location | Minneapolis, MN, US |
| Contact | Alex Zuniga |
| 510(k) history | 2 submissions · 2 cleared · 2020-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250910/> 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 14, 2026