

K150558 Eclipse SystemNov 12, 2015
253 days to decisionK150558 · Product code: **PJH** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k150558/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dynamic Rectal Control System (PJH) |
| Date received | Mar 4, 2015 |
| Decision date | Nov 12, 2015 |
| Days to decision | 253 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Pelvalon, Inc. |
| Location | Sunnyvale, CA, US |
| Contact | MILES ROSEN |
| 510(k) history | 1 submissions · 1 cleared · 2015-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150558/> 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 June 3, 2026