

K101535 BT-CATHJan 11, 2011
222 days to decisionK101535 · Product code: **OQY** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k101535/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intrauterine Tamponade Balloon (OQY) |
| Date received | Jun 3, 2010 |
| Decision date | Jan 11, 2011 |
| Days to decision | 222 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Utah Medical Products, Inc. |
| Location | Mchenry, IL, US |
| Contact | KEVIN CORNWELL |
| 510(k) history | 38 submissions · 38 cleared · 1979-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101535/> 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 23, 2026