

K162356 Vesair Cystoscopic SheathMar 2, 2017
191 days to decisionK162356 · Product code: **KNY** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k162356/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Accessories, Catheter, G-u (KNY) |
| Date received | Aug 23, 2016 |
| Decision date | Mar 2, 2017 |
| Days to decision | 191 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Solace Therapeutics |
| Location | Farmingham, MA, US |
| Contact | William Gruber |
| 510(k) history | 3 submissions · 3 cleared · 2013-2017 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162356/> 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 1, 2026