

**K053560 MODIFIED ENDOSHEATH SYSTEM FOR VSI FLEXIBLE
CYSTOSCOPE**Mar 16, 2006
85 days to decisionK053560 · Product code: **FAJ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k053560/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Cystoscope And Accessories, Flexible/rigid (FAJ) |
| Date received | Dec 21, 2005 |
| Decision date | Mar 16, 2006 |
| Days to decision | 85 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Vision-Sciences, Inc. |
| Location | Monrovia, CA, US |
| Contact | PAMELA PAPINEAU |
| 510(k) history | 33 submissions · 32 cleared · 1986-2011 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053560/> 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 19, 2026