

K151889 Infinity ERCP Sampling DeviceJul 30, 2015
20 days to decisionK151889 · Product code: **FDX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k151889/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Endoscopic Cytology Brush (FDX) |
| Date received | Jul 10, 2015 |
| Decision date | Jul 30, 2015 |
| Days to decision | 20 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|--|
| Company | United States Endoscopy Group, Inc. |
| Location | Mentor, OH, US |
| Contact | CARROLL MARTIN |
| 510(k) history | 94 submissions · 92 cleared · 1991-2020 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151889/> 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 15, 2026