

K122078 LOFRIC PRIMO, LOFRIC HYDRO-KITOct 31, 2012
107 days to decisionK122078 · Product code: **EZD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k122078/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Straight (EZD) |
| Date received | Jul 16, 2012 |
| Decision date | Oct 31, 2012 |
| Days to decision | 107 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Astra Tech, Inc. |
| Location | Waltham, MA, US |
| Contact | Allison C Komiyama |
| 510(k) history | 28 submissions · 28 cleared · 1994-2012 |

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