FDA 510(k) Premarket Notification

# K033023 INTERMITTENT URETHRAL CATHETERS

**CLEARED**

Dec 23, 2003
88 days to decision

K033023 · Product code: **KOD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k033023/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Urological (KOD) |
| Date received | Sep 26, 2003 |
| Decision date | Dec 23, 2003 |
| Days to decision | 88 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Rusch Intl.** |
| Location | Jeffrey, NH, US |
| Contact | RICK LYKINS |
| 510(k) history | 43 submissions · 43 cleared · 1995-2003 |