FDA 510(k) Premarket Notification

# K992137 UROLOGICAL CATHETER

**CLEARED**

Sep 3, 1999
71 days to decision

K992137 · Product code: **GBM** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k992137/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Urethral (GBM) |
| Date received | Jun 24, 1999 |
| Decision date | Sep 3, 1999 |
| Days to decision | 71 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Apogee, Inc.** |
| Location | Raleigh, NC, US |
| Contact | BRENT D ROBLING |
| 510(k) history | 2 submissions · 2 cleared · 1995-1999 |