FDA 510(k) Premarket Notification

# K884481 CLEAR SHOT ANGIOPLASTY BALLOON INFLATION DEVICE

**CLEARED**

Jan 10, 1989
80 days to decision

K884481 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k884481/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Angioplasty, Peripheral, Transluminal (LIT) |
| Date received | Oct 22, 1988 |
| Decision date | Jan 10, 1989 |
| Days to decision | 80 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Mallinckroot, Inc.** |
| Location | Argyle, NY, US |
| Contact | ROBERT S LAKE |
| 510(k) history | 7 submissions · 7 cleared · 1988-1999 |