FDA 510(k) Premarket Notification

# K043453 STERILEMED REPROCESSED IVUS IMAGING CATHETER

**CLEARED**

Mar 1, 2005
76 days to decision

K043453 · Product code: **OWQ** · Cardiovascular
Source: https://www.510kdatabase.net/k043453/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Reprocessed Intravascular Ultrasound Catheter (OWQ) |
| Date received | Dec 15, 2004 |
| Decision date | Mar 1, 2005 |
| Days to decision | 76 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Sterilmed, Inc.** |
| Location | Plymouth, MN, US |
| Contact | BRUCE LESTER |
| 510(k) history | 64 submissions · 64 cleared · 2001-2024 |