FDA 510(k) Premarket Notification

# K912172 SAFEWEDGE(TM) RELIEF VALVE DEVICE

**CLEARED**

Sep 27, 1991
134 days to decision

K912172 · Product code: **KRB** · Cardiovascular
Source: https://www.510kdatabase.net/k912172/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Probe, Thermodilution (KRB) |
| Date received | May 16, 1991 |
| Decision date | Sep 27, 1991 |
| Days to decision | 134 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Sunscope Intl., Inc.** |
| Location | Westlake Village, CA, US |
| Contact | KEITH CHAN |
| 510(k) history | 7 submissions · 7 cleared · 1991-2000 |