FDA 510(k) Premarket Notification

# K900459 APPLICARD (EKG)

**CLEARED**

Jul 31, 1990
182 days to decision

K900459 · Product code: **DRY** · Cardiovascular
Source: https://www.510kdatabase.net/k900459/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY) |
| Date received | Jan 30, 1990 |
| Decision date | Jul 31, 1990 |
| Days to decision | 182 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Medi-Globe Corp.** |
| Location | Irvine, CA, US |
| Contact | STEFAN WOHNHAS |
| 510(k) history | 18 submissions · 17 cleared · 1990-2006 |