FDA 510(k) Premarket Notification

# K915563 DIAGNOSTIC EP CATHETER

**CLEARED**

Mar 9, 1992
88 days to decision

K915563 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k915563/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF) |
| Date received | Dec 12, 1991 |
| Decision date | Mar 9, 1992 |
| Days to decision | 88 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Arrhythmia Technologies, Inc.** |
| Location | San Jose, CA, US |
| Contact | GEORGE SAVAGE |
| 510(k) history | 2 submissions · 2 cleared · 1992-1992 |