FDA 510(k) Premarket Notification

# K031174 BODY SIGNAL ECG ELECTRODE

**CLEARED**

Jul 10, 2003
87 days to decision

K031174 · Product code: **DRX** · Cardiovascular
Source: https://www.510kdatabase.net/k031174/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrode, Electrocardiograph (DRX) |
| Date received | Apr 14, 2003 |
| Decision date | Jul 10, 2003 |
| Days to decision | 87 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Wandy Rubber Industrial Co., Ltd.** |
| Location | Shi-Chih, Taipei, TW |
| Contact | JANIS YANG |
| 510(k) history | 4 submissions · 4 cleared · 2001-2013 |