



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 234417 Alive Technologies Pty Ltd - Single-channel electrocardiograph

ARTG entry for Medical Device Included Class IIa
Sponsor Alive Technologies Pty Ltd
Postal Address Unit 5 / 19 Expo Court, ASHMORE, QLD, 4214
 Australia
ARTG Start Date 4/03/2015
Product category Medical Device Class IIa
Status Active
Approval area Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name

AliveCor Inc

Address

Suite 600 / 30 Maiden Lane
 San Francisco, CA, 94108
 United States Of America

Products

1. Single-channel electrocardiograph

Product Type	Single Device Product	Effective date	4/03/2015
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GMDN 11413 Single-channel electrocardiograph

Intended purpose The AliveCor Heart Monitor is intended to be used by licensed medical professionals or patients to obtain single-lead electrocardiogram (ECG) rhythms.

Specific Conditions

No Specific Conditions included on Record

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