



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	355992	Apple Pty Ltd - Cardiac electrophysiology application software
ARTG entry for	Medical Device Included Class IIa	
Sponsor	Apple Pty Ltd	
Postal Address	Level 3 20 Martin Place, Sydney, NSW, 2000 Australia	
ARTG Start Date	2/03/2021	
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	Address
Apple Inc	One Apple Park Way Cupertino, CA, 95014 United States Of America

Products

1 . Cardiac electrophysiology application software

Product Type	Single Device Product	Effective Date	2/03/2021
GMDN	47699 Cardiac electrophysiology application software		
Intended Purpose	The ECG app is a software-only mobile medical application that is intended to be used with the Apple Watch to create, record, store, transfer and display a single-channel electrocardiogram (ECG) similar to a Lead I ECG. The ECG app determines the presence of atrial fibrillation (AF) or sinus rhythm on a classifiable waveform. The ECG app is not recommended for users with other known arrhythmias. The ECG app is intended for over-the-counter (OTC) use. The ECG data displayed by the ECG app is intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without consultation with a qualified health professional. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating AF from normal sinus rhythm and is not intended to replace traditional methods of diagnosis or treatment. The ECG app is not intended for use in people under 22 years old.		

Specific Conditions

No Specific Conditions included on Record

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