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
Apple Inc

Address
One Apple Park Way
Cupertino, CA, 95014
United States Of America

Products

1. Cardiac electrophysiology application software

Product Type
Single Device Product

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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