Summary for ARTG Entry: 240813

Integrated Sciences Pty Ltd - OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test and Kit Controls - HIV1/HIV2 antibody IVD, kit, immunochromatographic test (ICT), rapid

ARTG entry for Medical Device Included - IVD Class 4
Sponsor Integrated Sciences Pty Ltd
Postal Address PO Box 731, WILLOUGHBY, NSW, 2068
Australia
ARTG Start Date 5/06/2015
Product category Medical Device Class 4
Status Active
Approval area IVD

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 Orasure Technologies Inc
Address 220 East First Street
Bethlehem, PA, 18015-1360
United States Of America

Products

1. OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test and Kit Controls - HIV1/HIV2 antibody IVD, kit, immunochromatographic test (ICT), rapid

Product Type IVD
GMDN 48454 HIV1/HIV2 antibody IVD, kit, immunochromatographic test (ICT), rapid
Functional description The OraQuick ADVANCE ® HIV-1/2 Test is a manually performed, visually read, 20 minute immunoassay for the qualitative detection of antibodies to HIV-1 and HIV-2. The assay test strip, contains synthetic peptides representing the HIV envelope region and a goat anti-human IgG procedural control immobilized onto a nitrocellulose membrane in the Test (T) zone and the Control (C) zone, respectively
Intended purpose Intended to detect HIV antibodies in blood, oral fluid and plasma by ICT

Variant information

Specific Conditions
1. The person (the sponsor) in relation to whom the ‘OraQuick ADVANCE Rapid HIV-1/2 Antibody Test and Kit Controls’ (the Device) is included in the Australian Register of Therapeutic Goods (the ARTG) must ensure that the Device is only supplied for use by:
   a. laboratories that are accredited by the National Association of Testing Authorities (NATA) as medical testing laboratories and that participate in an HIV point of care quality assurance program; or
   b. organisations that:
      i. will perform, or supervise the performance of, HIV testing using the device; and
      ii. have received training in the delivery and administration of HIV testing in accordance with the requirements of the National HIV Testing Policy; and
   ii. have an established relationship (in relation to the referral and testing of specimens) with a NATA accredited medical testing laboratory; and
   iii. participate in an HIV point of care quality assurance program.
2. The sponsor of the ‘OraQuick ADVANCE Rapid HIV-1/2 Antibody Test and Kit Controls’ must make available training in the correct use of the Device and interpretation of results.
3. The sponsor must maintain records that demonstrate that the device has been supplied in compliance with condition 1 and that it has complied with condition 2.
4. The sponsor must provide to the Therapeutic Goods Administration (TGA) a post market surveillance report for each reporting period commencing on the date of inclusion of the device in the ARTG and ending at the end of the next 30 June and each twelve (12) months thereafter for the next five (5) financial years. Reports must be provided to the TGA before 1 October after each reporting period and must include the following: a. Numbers of tests sold in Australia and Worldwide
   b. Any adverse events including numbers of any reported false positive or false negative results in Australia and Worldwide.
   c. Reported problems or complaints associated with the use/interpretation of the device in Australia and Worldwide.
5. Post-market reports must be sent to the TGA at the following email address postmarketdevices@health.gov.au