Australian Government

Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	356740 Genome Investigation Pty Ltd - Interpretive software IVDs
ARTG entry for	Medical Device Included - IVD Class 3
Sponsor	Genome Investigation Pty Ltd
Postal Address	PO Box 2013, PORT MACQUARIE, NSW, 2444 Australia
ARTG Start Date	15/03/2021
Product Category	Medical Device Class 3
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	Address
Agendia NV	Science Park 406 , Amsterdam, 1098 XH Netherlands

Products

1 . Interpretive software IVDs

Product Type	IVD	**Effective Date**	15/03/2021
GMDN	CT910 Interpretive software IVDs		
Intended Purpose	The Agendia-secured Data Analysis Pipeline Tool (ADAPT) takes gene expression profiling data (.fastq file) from the MammaPrint breast cancer recurrence risk and BluePrint molecular subtyping Kit (see ARTG 356739) to generate both a breast cancer distant recurrence risk and a molecular subtype (luminal, basal or HER2) of the formalin-fixed, paraffin-embedded (FFPE) breast cancer tissue.		

Specific Conditions

No Specific Conditions included on Record

Public Summary

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Public Summary

Summary for ARTG Entry:	356739	Genome Investigation Pty Ltd - Acquired genetic alteration IVDs
ARTG entry for	Medical Device Included - IVD Class 3	
Sponsor	Genome Investigation Pty Ltd	
Postal Address	PO Box 2013, PORT MACQUARIE, NSW, 2444 Australia	
ARTG Start Date	15/03/2021	
Product Category	Medical Device Class 3	
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	Address
Agendia NV	Science Park 406 , Amsterdam, 1098 XH Netherlands

Products

1 . Acquired genetic alteration IVDs

Product Type	IVD	**Effective Date**	15/03/2021
GMDN	CT929 Acquired genetic alteration IVDs		
Intended Purpose	The MammaPrint breast cancer recurrence risk and BluePrint molecular subtyping NGS Kit is an in vitro diagnostic which generates data (.fastq file) from gene expression profiling of breast cancer tissue performed by next generation sequencing. This data is used to generate both a breast cancer distant recurrence risk and a molecular subtype (luminal, basal or HER2) via a second step using the Agendia-secured Data Analysis Pipeline Tool (ADAPT) (see ARTG 356740). The assay measures the gene expression profile on a next generation sequencer using RNA extracted from formalin-fixed, paraffin-embedded (FFPE) breast cancer tissue.		

Specific Conditions

No Specific Conditions included on Record

Public Summary