

K251916 GenBody COVID-19 Ag Home TestMar 13, 2026
263 days to decisionK251916 · Product code: QYT · Microbiology
Source: <https://www.510kdatabase.net/k251916/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Covid-19 Antigen Test (QYT)
Date received	Jun 23, 2025
Decision date	Mar 13, 2026
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Genbody.Inc.
Location	Cheonan-Si, KR
Contact	Han-bum Park
510(k) history	1 submissions · 1 cleared · 2026-2026

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