Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

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www.gov.uk/mhra

28th May 2021

Our Ref: DEU/005/2021/002

Dear Ms Pang and Mr Young

MEDICAL DEVICES REGULATIONS 2002 / MEDICAL DEVICE REGULATIONS (EU) 2017/745
AUTHORISATION OF SPECIAL USE OF Rapid COVID-19 (Antigen) Self-test

I refer to your letter dated 13/05/2020 in which you requested special approval to supply the above non-UKCA/CE marked medical devices on the UK Market, on the basis that a duly justified request has been made and this is in the interests of the protection of health. The reasons for the application cited:

"The Department of Health and Social Care (DHSC) has determined that the availability of Lateral Flow Device Self-tests is critical to the National Testing Programme in its emergency response to the Coronavirus pandemic and will also play a key role in managing the pandemic going forwards. To effectively monitor the pandemic, systematic screening and detection of both clinical and asymptomatic COVID-19 cases is critical. Particularly, the identification of subclinical or asymptomatic cases is important to reduce or stop the infection because these individuals may transmit the virus. Rapid COVID-19 Antigen Self-Test allows effective screening of COVID-19 infection. This objective requires a significant increase in the scale of testing that is undertaken in the general population. Distributed self-testing is likely a key approach that will achieve this. To deliver this scale of testing, distribution of Lateral Flow Device Self-tests, that are simple for a lay person to use, is an approach that will achieve this objective."

Based on this confirmation, the Secretary of State acting as the MHRA is satisfied that the request is duly justified, and that it is in the interests of the protection of public health to authorise the supply of the device to Great Britain under regulation 39(2) IVD of the Medical Devices Regulations 2002 and Northern Ireland under Article 59(1) of the Medical Device Regulations (EU) 2017/745, subject to the conditions set out below:

1. This authorisation commences on 28/05/2021 and ends on whichever of the following dates occurs soonest:

   a. 23/07/2021;

   b. the date when the device is UKCA/CE marked; or

   c. the date when UKCA/CE marked alternative product is available on the UK market.

   If this authorisation ends on 23/07/2021, and there continues to be a need for a further authorisation, the position will be reviewed by the MHRA.

2. That Orient Gene provides sufficient performance data that their test can be used in asymptomatic individuals as a self-test.

3. That during the granted period of this authorisation Orient Gene conducts a post market clinical follow up study for this test in asymptomatic individuals to gather data on the sensitivity and specificity of the device and demonstrating it can achieve suitable negative and positive predictive values as a self-test. The data must include numbers of tests undertaken along with results (including false positive and false negative) and with any serious adverse events. The protocol adopted and data gathered must be submitted to MHRA ahead of expiry date along with a formal request for an extension to the EUA. MHRA will then review the data submission and make a decision regarding granting an extension. A failure to provide the required data set ahead of the expiry date may result in the EUA being withdrawn.

4. That this authorisation is solely for testing to detect positive cases amongst asymptomatic people, one-off testing prior to an activity to reduce risks, outbreak testing and asymptomatic testing. Daily testing of contacts is not covered by this authorisation.

5. This authorisation is for the use of the Orient Gene packs of 7 tests as reviewed by MHRA. Orient Gene must inform MHRA prior to changing any of the components of the devices, including pack size.

6. That the devices are fit for purpose, and will work as intended in line with the stated performance and have been assessed as such.

7. That supply of the devices is only permitted to the Department of Health and Social Care as part of their planned deployment of COVID-19 tests in the UK. MHRA must be informed on the plan for distribution and roll-out.

8. That the recipients of the devices in question are supplied with the necessary Instructions for Use.

9. That any adverse events are reported and investigated where necessary.

10. That MHRA are consulted before any modifications are made to the Instructions for Use ensuring Orient Gene await MHRA's feedback before the proposed changes to the Instructions for Use are implemented and released. Orient Gene must ensure that:

- **a.** In the Instructions for Use the expression *'selftesting'* is corrected to *'self-testing';*
- **b.** MHRA has oversight of the video specific to Orient Gene prior to any distribution of the test;
- **c.** The purpose of the product codes specified in the Instructions for Use are clarified.
- **d.** That the back page of the Instructions for Use includes the contact details of the UK Responsible Person for Orient Gene.

11. That Orient Gene has implemented a robust Quality Management System ensuring full control in the adopted system.

12. That Orient Gene has implemented a robust Risk Management System appropriate for the self-test kit under this authorisation.

13. That you agree to the details of the authorisation being listed on MHRA's website to confirm the manufacturer and products authorised under this exemption including the issue date and duration.

14. That you submit to the MHRA a detailed time plan for UKCA/CE marking of the device.

15. That after four weeks you submit to the MHRA a report detailing, a summary of adverse incidents whilst under this authorisation, the number of devices supplied and to whom; the manufacturer must keep track of every device down to the end user through their distribution network. This must be included in the report to MHRA.

16. That at the end of the authorisation period Orient Gene will cease the supply of any devices under the authority of this authorisation unless an extension is granted.

17. That Orient Gene conduct suitable verification prior to supply of the tests, including regular use of controls and a blinded sample panel for the verification of product.

18. That you fulfil MHRA requirements to conduct fortnightly monitoring for variants against the available information on GISAID and that both favourable and unfavourable data should be reported to the MHRA as assurance of either positive or negative performance. This is in line with MHRA expectations that manufacturers should submit a monthly update (on the second week of each month) for in silico assurance of assay performance. MHRA regards variants as a serious public health threat and any potential concerns should be reported to MHRA within 48 hours.

19. Orient Gene must have a Post Market Surveillance plan and a robust Quality Management System to collect and evaluate any complaint received in relation to compromised safety, quality or performance of the device and undertake the necessary corrective and preventive actions such initiating and undertaking recall of products if a safety action is identified. Orient Gene should collaborate with the Department of Health and Social Care to fulfil this condition successfully.

20. That within three weeks, you submit your Post Market Surveillance plan for monthly reports to MHRA including the following:

- **a.** Results and conclusions of the analyses of the post market surveillance data gathered (e.g. report of ALL complaints plus report of those considered to be reportable as vigilance);
- **b.** A rationale and description of any preventive and corrective actions taken;
- **c.** The conclusions of the benefit-risk determination;

d. The main findings of the post market performance study;

e. The volume of devices supplied, an estimate of the size and other characteristics of the population using the device and the usage frequency of the devices.

21. That Orient Gene as a legal manufacturer consider issuing Field Safety Corrective Action, when the need arises.

22. That Orient Gene gather evidence* through a Proactive Post Market Surveillance plan to survey user experience to monitor events such as:

a. Material break (if something breaks during use);
b. Detachment of device component (for example, if the swab head of the swab falls off);
c. Component missing (if something in the kit is missing);
d. Packaging problem;
e. Unable to obtain readings (e.g. void results or if the user is unsure of the result);
f. Failure to obtain sample;
g. Inadequate instructions;
h. Negative clinical effect associated to the test, e.g. cuts, nose bleeds etc;

*Including Details of the test kit (e.g. brand name/model, Lot/batch, barcode number) to help with traceability when investigating incidents.

23. That in addition to the summative reporting detailed in Condition 15, Orient Gene agrees to provide full details of any serious adverse incidents that occur in relation to the device or the use of the device in addition to the normal procedures (as detailed in the vigilance reporting guidelines) for reporting such incidents to the MHRA.

24. That Orient Gene agrees to provide details to the users that any adverse incidents that occur in relation to the device or the use of the device are reported via the Yellow Card Scheme found at https://coronavirus-yellowcard.mhra.gov.uk in addition to meeting your obligations for reporting as legal manufacturer (see Condition 21).

25. Orient Gene understands that failure to adhere to any of the conditions stipulated will result in this authorisation being removed.

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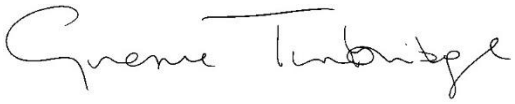
Please take this letter as formal approval. Please contact Devices.ExceptionalUse@mhra.gov.uk if you require any clarification in relation to this process.

Yours sincerely



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