



Medicines & Healthcare products
Regulatory Agency

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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2026/00985**

28 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 29 August 2026. You wrote:

I am writing as a member of the public with concerns regarding the regulatory status, clinical safety and post-market surveillance of Rapid Health Smart Triage, which is being deployed within NHS primary care.

I understand that Smart Triage is software used to assess information supplied by patients and to determine or influence the urgency, routing and/or timeframe in which patients receive healthcare.

I would be grateful if this correspondence could be forwarded to the MHRA team responsible for software as a medical device, medical-device compliance and post-market safety surveillance.

I am not requesting confidential patient information or proprietary source code. I am seeking to understand the regulatory safeguards that apply to a system capable of influencing when patients receive clinical attention.

1. Medical-device registration

Please confirm whether Rapid Health Smart Triage is currently registered with the MHRA as a medical device.

If so, please provide or confirm:

- * the registered manufacturer;*
- * device name;*
- * MHRA registration/reference number;*
- * stated intended purpose;*
- * medical-device classification;*
- * UKCA/CE status; and*
- * date of registration.*

2. Device classification

Please explain which medical-device risk classification applies to Smart Triage and the regulatory basis for that classification.

In particular, does its intended purpose encompass assessing symptoms and determining or recommending the urgency, routing or timeframe for medical attention?

If so, I would be grateful for clarification as to how that functionality was taken into account when determining the appropriate device classification.

3. Nature of the technology

Rapid Health and NHS material have described Smart Triage using terms including AI and automated/autonomous triage.

Please advise what information the MHRA holds concerning whether Smart Triage uses:

- * artificial intelligence;
- * machine learning;
- * a large language model;
- * generative AI;
- * deterministic/rules-based clinical decision logic; or
- * another form of automated clinical decision-making.

If the device is predominantly rules-based rather than machine-learning based, please explain whether this affects its regulatory classification or the clinical evidence required.

4. Clinical evidence

What clinical evidence is required for software of this type to demonstrate that it performs its intended purpose safely?

In the case of Smart Triage specifically, does the MHRA hold or has it reviewed evidence concerning:

- * sensitivity for urgent and emergency presentations;
- * false-negative rates;
- * under-triage rates;
- * over-triage rates;
- * red-flag detection;
- * comparison with assessment by qualified clinicians; and
- * performance in children, elderly patients and other vulnerable groups?

If such evidence is held and can be disclosed, please identify or provide it.

If the MHRA does not itself review this evidence before registration of a device of this classification, I would be grateful if you could explain this clearly and identify who is responsible for assessing it.

5. Clinical evaluation

Is Rapid Health required to maintain a Clinical Evaluation Report or equivalent clinical evaluation for Smart Triage?

If so, what type and level of clinical evidence is required to support the manufacturer's conclusion that the benefits of the system outweigh its clinical risks?

Does the MHRA independently review that Clinical Evaluation Report?

6. Under-triage as a device safety risk

I am particularly concerned about the possibility of under-triage.

If software determines that a patient does not require urgent medical attention, but the patient subsequently proves to have a serious or time-critical condition, would this potentially constitute a medical-device adverse incident or near miss reportable to the MHRA?

Similarly, would a failure by the software to recognise a clinically significant red flag potentially constitute a reportable medical-device incident?

7. Adverse incidents involving Smart Triage

Has the MHRA received Yellow Card reports, manufacturer vigilance reports or other reports concerning Rapid Health Smart Triage?

In particular, have reports concerned:

- * under-triage;
- * delayed medical attention;
- * incorrect urgency assessment;
- * failure to recognise red-flag symptoms;
- * incorrect routing;
- * emergency hospital treatment following a lower-urgency triage outcome;
- * serious patient harm; or

- * death?

I appreciate that information about individual patients cannot be disclosed.

However, I would be grateful if the MHRA could provide aggregate numbers and categories of reports concerning this product where legally possible.

8. Manufacturer's reporting obligations

Please explain Rapid Health's obligations to report adverse incidents and safety signals concerning Smart Triage to the MHRA.

In particular:

- * *What types of under-triage incidents must be reported?*
- * *What are the applicable reporting timescales?*
- * *Is Rapid Health required to monitor trends in less serious incidents or near misses?*
- * *Is the manufacturer required to notify the MHRA when clinical decision rules are changed in response to safety incidents?*

9. Post-market surveillance

What post-market surveillance is required for Smart Triage?

Is Rapid Health required to monitor the real-world performance of its triage system after deployment?

Does that surveillance specifically need to measure or identify:

- * *under-triage;*
- * *false negatives;*
- * *red-flag failures;*
- * *differences between automated triage and subsequent clinician assessment; and*
- * *differences in performance between patient groups?*

10. Changes to clinical decision rules

If Rapid Health changes the clinical rules determining urgency or patient routing, what regulatory process applies?

At what point would a change to those rules constitute a significant modification requiring further clinical evaluation, regulatory assessment or notification to the MHRA?

11. Patients and Yellow Card reporting

Please confirm whether a patient or member of the public can submit a Yellow Card medical-device report where they believe Smart Triage:

- * *incorrectly assessed their urgency;*
- * *delayed access to appropriate medical care;*
- * *failed to identify serious symptoms; or*
- * *otherwise affected their diagnosis or treatment.*

If so, I would be grateful if you could confirm the appropriate reporting route.

12. Regulatory responsibility

Finally, I would appreciate clarification of an important point of accountability.

When medical-device software autonomously determines or influences the urgency with which an NHS patient receives medical attention, which organisation is responsible for demonstrating that the algorithm or clinical decision rules are sufficiently safe for that intended purpose?

In the case of Smart Triage, is that determination made by:

- * *Rapid Health as manufacturer;*
- * *the MHRA;*
- * *an Approved Body;*
- * *NHS England;*
- * *the NHS organisation deploying the software; or*
- * *some combination of these organisations?*

I would be particularly grateful if you could explain which organisation has actually examined the clinical performance evidence demonstrating that Smart Triage can safely

distinguish patients who can wait from those requiring urgent medical attention.

13. Regulatory review

Given the increasingly widespread deployment of automated triage systems within NHS primary care, has the MHRA undertaken, or does it intend to undertake, any specific review of the clinical safety of Rapid Health Smart Triage or comparable automated triage systems?

If concerns about a particular deployment or patient experience should instead be submitted through the Yellow Card scheme, please advise accordingly.

Thank you for considering these questions.

My purpose in contacting the MHRA is to understand the regulatory chain by which software capable of influencing the urgency of NHS patient care is demonstrated to be safe, and how possible failures are detected and investigated once that software is in widespread clinical use.

I would be grateful for a substantive response or for this correspondence to be forwarded to the appropriate medical-device safety and compliance team.

MHRA Response

We can confirm we have searched our records and consulted relevant subject matter experts, confirm that we do hold some the requested information. However, some of this information is exempt from disclosure.

The FoI Act provides a legal right of access to recorded information held by a public authority like the MHRA, subject to certain exemptions that may apply. The Act does not oblige a public authority to create new information to answer questions; nor does it require a public authority to give an opinion or explanation, generate answers to questions, or create or obtain information it does not hold.

If you ask a question, we will provide you with the recorded information that best answers the question. Once we have provided the recorded information, we have met our obligations under the Act.

Please see our responses to each of your questions below.

1. Medical device registration

This information is exempt under Section 21 of the FOI Act as this information is already available to you through the Public Access Registration Database (PARD). A link to this is provided below.

<https://pard.mhra.gov.uk/>

For your convenience, please see below the link to Rapid Health Limited's details on the PARD.

<https://pard.mhra.gov.uk/manufacturer-details/36231> (please scroll down on the page to see the relevant information)

2. Device classification

Please see our response to Question 1 above.

3. Nature of the technology

Please see our response to Question 5 below and also the below:

Nature of the technology is broadly described by the GMDN Term. The Description for this GMDN Code and Term (64275) is: *An Internet-based software program intended to be used on a non-medical computerized device, by a patient in a non-clinical environment, to provide general health assessment information and/or health advice through an interactive platform; it is not dedicated to a specific condition. The software is intended to collect patient information (demographics, lifestyle data, and/or symptoms) and feedback information to indicate the*

general health/wellness in key areas (e.g., mental, cardiovascular) and/or assist the patient in deciding the best course of action if they are unwell (e.g., see a clinician, self-treatment for minor ailments). It does not communicate with a clinician.

4. Clinical evidence

Please see our response to Question 5 below.

5. Clinical evaluation

Our Reply:

A manufacturer should be able to demonstrate that there is sufficient clinical evidence to support the device's claimed safety, performance and benefit-risk profile for its stated intended purpose, and that this evidence is appropriately documented, evaluated and kept under review.

Please note that the MHRA does not itself assess or approve medical devices placed on the UK market, please see the guidance regarding the [UKCA mark and Conformity Assessment Bodies](#).

Information with regards to manufacturers of Class I devices and their responsibilities are outlined here: [Guidance on Class I medical devices](#)

The MHRA may hold certain information about a device where it has been submitted to the Agency for a specific regulatory purpose, such as registration, vigilance, compliance, enforcement, clinical investigation, or other regulatory activity. However, MHRA's role as regulator does not mean that it routinely holds a manufacturer's full technical file or quality management documentation for every device placed on the market. On this basis we have determined that there is no reasonable avenue to search for the requested information, and therefore we consider that the requested information is not held.

6. Under-triage as a device safety risk

Our reply:

"[...] the possibility of under-triage. If software determines that a patient does not require urgent medical attention, but the patient subsequently proves to have a serious or time-critical condition, would this potentially constitute a medical-device adverse incident or near miss reportable to the MHRA?"

You have asked a question in this part of your request rather than for recorded information and as such we are under no obligation to respond to this part of the request.

We have however provided the following outside our obligation under the Act that, as this may be helpful to you.

This would be reportable by the manufacturer, user, or other healthcare professional. There is information on the Yellowcard website which describes what software incidents are reportable: <https://yellowcard.mhra.gov.uk/> and there is MHRA guidance on the Yellowcard scheme as well <https://www.gov.uk/guidance/the-yellow-card-scheme-guidance-for-healthcare-professionals-patients-and-the-public>

7. Adverse incidents involving Smart Triage

Our reply:

We can confirm up to and including 15th September 2026 the Yellow Card scheme has not received any adverse incident reports concerning the Rapid Health Smart Triage. Therefore, we hold no recorded information to meet your request.

8. Manufacturer's reporting obligations

Our Reply:

This information is exempt under Section 21 of the FOI Act as this information is already available to you through Information about reporting adverse incidents is available on the MHRA webpages: [MHRA guidance on new Medical Devices Post-Market Surveillance requirements - GOV.UK](#)

9. Post-market surveillance

Our Reply:

This information is exempt under Section 21 of the FOI Act as this information is already accessible to you, information on post market surveillance requirements is available on the MHRA webpages: [MHRA guidance on new Medical Devices Post-Market Surveillance requirements - GOV.UK](#)

10. Changes to clinical decision rules

Our Reply:

This information is exempt under Section 21 of the FOI Act as this information is already available to you through Information is available in the MHRA software flowchart, page 27 in particular you may find useful: [MHRA Software flowchart](#)

11. Patients and Yellow Card reporting

Our Reply:

You have asked a question in this part of your request rather than for recorded information and as such we are under no obligation to respond to this part of the request.

We have however provided the following outside our obligation under the Act that, as this may be helpful to you.

Patients and members of the public can report adverse incident report involving medical devices, including software-based medical devices such as the Rapid Health Smart Triage, through the Yellow Card scheme. Reports can be submitted online via the MHRA website if they believe the device may have contributed to harm, an incorrect assessment, or another safety concern. Further information and reporting details are available at the Yellow Card scheme website:

[Yellow Card | Making medicines and medical devices safer](#). Additionally, they can send us an email at yellowcard@mhra.gov.uk, or call our Yellow Card Information Service on 0808 100 3352 (9am to 5pm Monday-Friday).

12. Regulatory responsibility

Our reply to 12: Please see response to question 5, and also refer to;

<https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#ukcamark-and-conformity-assessment-bodies>

13. Regulatory review

Our Reply:

Please see response to Q5 and Q11

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113.

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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>