

[Redacted]

From: [Redacted]
Sent: Monday, 14 August 2023 1:00 PM
To: Device Reforms
Subject: Public consultation - proposed application audit framework for medical devices

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Hello

[Redacted] would like to provide a response to the public consultation on the proposed audit framework for medical devices.

Proposal 1 – The proposal to publish a set of risk factors that will influence the likelihood for a medical device to be selected for an audit is considered reasonable.

Proposals 2-5 do not apply to our company at this time.

Proposal 6 is considered reasonable, as long as there is clear feedback on what was missing/needs further information from the submission. Potentially the opportunity for a discussion with the reviewer for clarification.

Proposal 7 greater visibility of timeframes would be welcomed. The suggestion of the updates at specific milestones in the process would be beneficial to be able to manage expectations and work flow dependent on the application approval.

Regards

[Redacted]

[Redacted]@ [Redacted]
[Redacted] [Redacted] [Redacted] [Redacted]
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