Classification of Attention Task Performance Recorders
FDA Questions

Neurological Devices Panel of the Medical Devices Advisory Committee June 3-4, 2021

1. FDA has identified the following risks to health for attention task performance recorders intended to 1) measure reaction time and associated patient performance in response to attention tasks and 2) aid in assessment or diagnosis of specific diseases or conditions.

Risks to Health and Descriptions/Examples for Attention Task Performance Recorders Intended to Measure Reaction Time and Associated Patient Performance in Response to Attention Tasks, Without Aiding in Assessment or Diagnosis

Identified Risk	Description/Examples
Patient discomfort (e.g., visual or mental fatigue)	• Use of the devices can cause patient discomfort, such as visual or mental fatigue.
Incorrect or inaccurate measurements of reaction time or other attention tasks	• Use of the devices can result in incorrect or inaccurate measurements of reaction time or other attention tasks based on associated patient performance

Risks to Health and Descriptions/Examples for Attention Task Performance Recorders Intended to Aid in Assessment or Diagnosis of Specific Diseases or Conditions

Identified Risk	Description/Examples
Patient discomfort (e.g., visual or mental fatigue)	• Use of the devices can cause patient discomfort, such as visual or mental fatigue.
Incorrect or inaccurate results leading to inaccurate assessment or delayed diagnosis, both of which could result in inappropriate therapy or delay in treatment	• A false positive result means that the device indicates the patient has the clinical condition or disease of interest, such as ADHD or be at risk of cognitive impairment, when in fact none is present. • A false negative result means that the device indicates the patient does not have the clinical condition or disease of interest, such as ADHD or be at risk of cognitive impairment, when in fact the clinical condition or disease is present.

Please comment on whether you agree with inclusion of all the risks in the overall risk assessment of attention task performance recorders under product code "LQD". In addition, please comment on whether you believe that any additional risks should

be included in the overall risk assessment of these attention task performance recorders.

2. Section 513 of the Food, Drug, and Cosmetic Act states a device should be Class III if:

    - insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of special controls would provide such assurance, AND

    - if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

    A device should be Class II if:

    - general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness, AND

    - there is sufficient information to establish special controls to provide such assurance.

    A device should be Class I if:

    - general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
    - insufficient information exists to:
        - determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
        - establish special controls to provide such assurance, BUT
            I. is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and
            II. does not present a potential unreasonable risk of illness or injury.

    FDA believes general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness and sufficient information exists to establish special controls to adequately mitigate the risks to health and provide reasonable assurance of device safety and effectiveness for this device type. As such, FDA believes that Class II is the appropriate classification for attention task performance recorders. Following are risk/mitigation tables, which outline the identified risks to health for this device type and the recommended controls to mitigate the identified risks, delineated by intended use:

Risk/mitigation recommendations for attention task performance recorders <u>intended to measure reaction time and associated patient performance in response to attention tasks only, without aiding in assessment or diagnosis</u>

Identified Risk	Recommended Mitigation Measure
Patient discomfort (e.g., visual or mental fatigue)	• Labeling
Incorrect or inaccurate measurements of reaction time or other attention tasks	• Non-clinical performance testing • Software verification, validation, and hazard analysis • Labeling

Risk/mitigation recommendations for attention task performance recorders <u>intended to measure reaction time and associated patient performance in response to attention tasks</u>

Identified Risk	Recommended Mitigation Measure
Patient discomfort (e.g., visual or mental fatigue)	• Labeling
Incorrect or inaccurate results leading to inaccurate assessment or delayed diagnosis, both of which could result in inappropriate therapy or delay in treatment	• Clinical performance testing • Non-clinical performance testing • Software verification, validation, and hazard analysis • Labeling

a. **Please discuss whether the identified special controls appropriately mitigate the identified risks to health for attention task performance recorders *intended to measure reaction time and associated patient performance in response to attention tasks only, without aiding in assessment or diagnosis*. Please also discuss whether additional or different special controls are recommended.**

1. The technical parameters of the device's hardware and software must be fully characterized and be accompanied by appropriate non-clinical testing:
    a. Hardware specifications must be provided. Appropriate verification, validation and hazard analysis must be performed, including applicable electrical safety testing.
    b. Software, including any proprietary algorithm(s) used by the device to measure reaction time and output other measures of attention, associated activities and related task performance, must be described in detail in the Software Requirements Specification (SRS) and Software Design Specification (SDS). Appropriate software verification, validation and hazard analysis must be performed.

2. Non-clinical device performance evaluation must demonstrate accurate and precise measurement of patient reaction times in response to task stimuli.

3. The labeling must include:
    a. A warning that the device is not intended to aid in patient assessment or diagnosis of specific diseases or conditions.
    b. Any instructions technicians must convey to patients regarding safe and effective administration of the specific tasks and collection of task performance data.

b. **Please discuss whether the identified special controls appropriately mitigate the identified risks to health for attention task performance recorders *intended to measure reaction time and associated patient performance in response to attention tasks for the aid in assessment or diagnosis of specific diseases or conditions*. Please also discuss whether additional or different special controls are recommended.**

1. Clinical device performance evaluation must validate that the device outputs accurately and precisely assess patient symptomology associated with the specific disease or condition for which the device is intended to assess or diagnose. The testing must:
    a. Evaluate agreement between device output and patient symptomology.
    b. Evaluate device test-retest reliability.
    c. Describe construction of any normative or reference database, which includes the following:
        i. How the clinical work-up was completed to define the reference population, including the establishment of inclusion and exclusion criteria.
        ii. Statistical methods and model assumptions used.

2. The technical parameters of the device's hardware and software must be fully characterized and be accompanied by appropriate non-clinical testing:
    a. Hardware specifications must be provided. Appropriate verification, validation and hazard analysis must be performed, including applicable electrical safety testing.
    b. Software, including any proprietary algorithm(s) used by the device to measure reaction time and output other measures of attention, associated activities and related task performance, must be described in detail in the Software Requirements Specification (SRS) and Software Design Specification (SDS). Appropriate software verification, validation and hazard analysis must be performed.

3. Non-clinical device performance evaluation must demonstrate accurate and precise measurement of patient reaction times in response to task stimuli.

4. The labeling must include:
    a. A summary of any clinical testing conducted to demonstrate that the device outputs accurately and precisely assess patient symptomology

associated with the specific disease or condition for which the device is intended to assess or diagnose. The summary of testing must include the following:

i. Agreement between device output and patient symptomology.
ii. Device test-retest reliability.
iii. A description of any normative or reference database, which includes the following:
    1. How the clinical work-up was completed to define the reference population, including the establishment of inclusion and exclusion criteria.
    2. How reference values will be reported to the user.
    3. Representative screenshots and reports that will be generated to provide the user results and reference data.
    4. Statistical methods and model assumptions used.
    5. Whether or not the database was adjusted due to differences in age, gender, or other factors.

b. A warning that the device is intended to aid in patient assessment or diagnosis by a trained physician and is not intended for stand-alone use.
c. Any instructions that technicians must convey to patients regarding safe and effective administration of the specific tasks and collection of task performance data.

3. **Please discuss whether you agree with FDA's proposed classification of Class II with special controls for attention task performance recorders. If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.**