Classification of Optical Contour Sensing Devices
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 optical contour sensing devices:

Identified Risk	Description/Examples
Device failure/malfunction leading to inaccurate results and diagnosis	Device error may present inaccurate results to the user, leading to misdiagnosis, inadequate or improper patient management, or worsening of the condition.
Use error leading to inaccurate results and diagnosis	Use error may present inaccurate results to the user, leading to misdiagnosis, inadequate or improper patient management, or worsening of the condition.

Please comment on whether you agree with inclusion of all the risks in the overall risk assessment of optical contour sensing devices under product code "LDK". In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these optical contour sensing devices.

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 does not believe that special controls will be required for optical contour sensing devices under product code "LDK" and that general controls will be sufficient to provide a reasonable assurance of the safety and effectiveness for acupressure devices. As such, FDA believes that Class I is the appropriate classification for optical contour sensing devices under product code "LDK."

Please discuss whether you agree with FDA's proposed classification of Class I with general controls for optical contour sensing devices under product code "LDK." If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.