Classification of Optical Contour Sensing Devices Under Product Code "LDK"

Presenter
Kiyana Weatherspoon
Division of Neuromodulation and Physical Medicine Devices
Office of Health Technology 5-Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
Food and Drug Administration

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Device Description

- Optical contour sensing devices are intended for measuring anatomical landmarks (e.g., spine, foot).
- Intended for medical purposes, for example:
  - Monitoring/detection of musculoskeletal balance, posture, and vertebral curvature
  - Quantification of body angles related to postural asymmetries
- Devices may utilize:
  - optical systems such as a camera or optical scanner
  - sensors and software for anatomical evaluation and assessment

Indications for Use

- Most devices under product code LDK are cleared for over-the-counter use.
- Representative indications for use for these devices include:
  - Quantify angles on digital photograph depictions such as body angles related to postural asymmetries
  - Detect and monitor scoliosis
  - Screen and monitor scoliosis, lordosis and kyphosis
  - Provide topographical images to assist in the assessment of postural asymmetries
  - Evaluate musculoskeletal balance, posture and vertebral curvature
  - Measure surface manifestations of the internal parameters of kyphosis, lordosis, and Cobb angle.

Regulatory History

- Pre-amendment, i.e., marketed prior to May 1976
- Unclassified when marketed
- These devices are being regulated through the 510(k) pathway and are cleared for marketing if their intended use and technological characteristics are “substantially equivalent” to a legally marketed predicate device. Since these devices are unclassified, there is no regulation associated with the product code.
- The following 6 devices under the LDK product code have been cleared:

510(k) Number	**Device Name**
K183485	CryoVizion System
K923792	Quantec Spinal Measurement System
K860225	Metricom
K851133	Terran Biomechanical Analysis System
K844736	ISIS
K800591	Contourograph M-500

Clinical Background

- Scoliosis is a lateral curvature of the spine that is greater than 10°
- Kyphosis is a forward curvature of the thoracic spine beyond the normal range of 30 – 50°
- Lordosis is a backwards curvature of the cervical and lumbar spine when viewed in the sagittal plane
- Etiology of scoliosis is not well understood
  - May arise in adolescents idiopathically with genetic factors
  - Consequence of degenerative changes in adults
  - May arise secondary to underlying medical condition such as osteoporosis, for example

Clinical Background

Management

- Individualized according to etiology, deformity severity, and symptom severity
  - Nonnarcotic analgesics
  - Physical exercises
  - Injection therapies such as epidural glucocorticoid injection
  - Surgical intervention

Literature Review

- A systematic literature review was conducted in an effort to gather and assess published information regarding the safety and effectiveness of optical contour sensing devices under product code “LDK".
- Initial online literature searches from January 1, 2010 to December 31, 2020 were performed.
- The search was limited to human studies that assessed the safety or effectiveness of the cleared devices, that were published in English, and publications that were not systematic literature review.
- This initial search resulted in a total of 48 publications. However, none of the publications were related to the assessment of safety or effectiveness of optical contour sensing devices.

Literature Review

- A second search was conducted using the same search terms but using a different time period from 1980 to 1990 when the devices were first cleared.
- This search resulted in a total of 6 publications after the first screening.
  - Similarly, none of the publications met the inclusion criteria as they were not related to the assessment of the safety or effectiveness of the optical contour sensing devices.
- A third search of publications up until September 1, 2020 was conducted, using PubMed and Embase, based on device brand names.
- As of September 1, 2020, the search by device brand names resulted on 140 English publications of human studies. All were screened by the following inclusion criteria:
  1. inclusion of device name in the publication
  2. assessed device safety and effectiveness in scoliosis diagnosis
- After applying these two inclusion criteria, ten relevant articles were identified for inclusion in this evidence assessment.

Literature Review – Safety Assessment

- Most publications did not directly assess safety, but optical contour sensing devices are generally recognized as low risk because of the non-invasive nature of the devices and non-exposure to radiation.
- In the publications included in the literature review, it was widely acknowledged that replacing X-ray with optical contour sensing devices for scoliosis diagnosis would lower the exposure to radiation and thus could achieve a favorable safety outcome.

Literature Review – Effectiveness Assessment

- A few publications argued that optical contour sensing devices should not replace X-ray for scoliosis diagnosis because there was evidence suggesting that some devices can be inaccurate.
- However, most of the publications included in this review reported results favoring optical contour sensing devices for scoliosis diagnosis in place of X-rays.

Literature Review – Summation

- The published medical literature suggests that optical contour sensing devices can replicate X-ray in the diagnosis of scoliosis. Most of the identified publications did not assess safety, but it was widely acknowledged that replacing X-ray with optical contour sensing devices for scoliosis diagnosis minimizes radiation exposure.
- It should be noted that this literature review is limited. The first two systematic searches using pre-specified terminology did not return any relevant publications given that the results from these searches were not related to the assessment of safety or effectiveness of optical contour sensing devices.
- The conclusions here are based on publications identified based on brand name specific searches which focused on assessing safety and effectiveness in scoliosis diagnosis.

Medical Device Reports

Medical Device Reporting (MDR): the mechanism for the FDA to receive significant medical device adverse events from:

- mandatory reporters (manufacturers, importers and user facilities)
- voluntary reporters (health care professionals, patients, consumers)

MDR reports can be used effectively to:

- Establish a qualitative snapshot of adverse events for a specific device or device type
- Detect actual or potential device problems used in a “real world” setting/environment, including:
  - rare, serious, or unexpected adverse events
  - adverse events that occur during long-term device use
  - adverse events associated with vulnerable populations
  - off-label use
  - user error

Medical Device Reports

Limitations

- Under reporting of events
- Potential submission of incomplete, inaccurate, untimely, unverified, or biased data
- Incidence or prevalence of an event cannot be determined from this reporting system alone
- Confirming whether a device caused a specific event can be difficult based solely on information provided in a given report
- MAUDE (Manufacturer and User Facility Device Experience) data does not represent all known safety information for a reported medical device

Medical Device Reports

- MAUDE Database reviewed for the LDK product code “LDK” from April 1, 1980, through December 31, 2020:
  - No Medical Device Reports were identified.

Recall History

- The Medical Device Recall database contains Medical Device Recalls classified since November 2002.
- Since January 2017, it may also include correction or removal actions initiated by a firm prior to review by the FDA.
- The status is updated if the FDA identifies a violation and classifies the action as a recall and again when the recall is terminated.
- FDA recall classification (resulting in the posting date) may occur after the firm recalling the medical device product conducts and communicates with its customers about the recall.

Recall History

- A review of the database found no recalls for devices under the LDK product code.

Risks

The following probable risks were identified by FDA:

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.

Proposed Classification Regulation

890.2000 Optical contour sensing device

(a) *Identification*.

An optical contour sensing device is intended for measuring various anatomical landmarks for medical purposes, such as to detect abnormalities associated with postural asymmetry. The device may consist of optical system(s) such as a camera, optical scanner, or other optical unit, and may also utilize sensors and software for anatomical evaluation and assessment

(b) *Classification*.

Class I (general controls).

Thank You

Questions to Panel - LDK

Question 1 to Panel

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.

Question 2 to Panel

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
- 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.

Question 2 to Panel

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
    - 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
    - does not present a potential unreasonable risk of illness or injury.

Question 2 to Panel

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 optical contour sensing 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.

End of Panel Questions for Product Code “LDK”