# FDA Executive Summary

Prepared for the June 3-4, 2021 Meeting of the Neurological Devices Panel

Classification of Optical Contour Sensing Devices

Product Code: LDK

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# 1. Introduction

Per Section 513(b) of the Food, Drug, and Cosmetic Act (the Act), the Food and Drug Administration (FDA) is convening the Neurological Devices Advisory Panel (the Panel) for the purpose of obtaining recommendations regarding the classification of optical contour sensing devices, a pre-amendments device type which remains unclassified. Specifically, the FDA will ask the Panel to provide recommendations regarding the regulatory classification of optical contour sensing devices under product code "LDK." The device names and associated product codes are developed by the Center for Devices and Radiological Health (CDRH) in order to identify the generic category of a device for FDA. While most of these product codes are associated with a device classification regulation, some product codes, including "LDK," remain unclassified.

FDA is holding this panel meeting to obtain input on the risks to health and benefits of optical contour sensing devices under product code "LDK." The Panel will discuss whether optical contour sensing devices under product code "LDK" should be classified into class I (subject only to General Controls).

## 1.1 Current Regulatory Pathways

Optical contour sensing devices are a pre-amendments, unclassified device type. This means that this device type was marketed prior to the Medical Device Amendments of 1976 but was not classified by the original classification panels. Currently 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.

## 1.2 Device Description

Optical contour sensing devices are intended for measuring various anatomical landmarks (e.g., spine, foot) for medical purposes, for example to monitor and detect musculoskeletal balance, posture and vertebral curvature, and also quantify body angles related to postural asymmetries. 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.

The first cleared optical contour sensing device employed the projection of a Moiré pattern on the subject's back to produce a topographical image of back contours that was captured in a photograph. All other cleared optical sensing devices use computer technology to scan and compute coordinates of the subject's surface topography and create digitized images.

While all other devices capture images from a static subject, one of the devices cleared under this product code evaluates a moving subject, monitoring infrared

markers that have been attached to patient's hip, thigh, knee, shin and several points on the foot to measure leg function while walking on a treadmill.

## 2. Regulatory History

The Contourograph M-500 marketed by Bio-Tek Instruments Incorporated was the first optical contour sensing device cleared by FDA on April 2, 1980 under product code LDK. The sponsor cited substantial equivalence of their device to the Moiré Contourograph marketed by Atomic Energy of Canada Ltd, a pre-amendments device which was distributed prior to 1976. The FDA has cleared six optical contour sensing devices to date. These optical contour sensing devices are primarily cleared for over the counter (OTC) use.

See Table 1 for a listing of the manufacturers, device names, and associated 510(k) submission numbers for cleared optical contour sensing devices under product code "LDK":

**Table 1: 510(k) Clearances for Optical Contour Sensing Devices under Product Code "LDK"**

| 510(k) Number | Trade Name | Sponsor |
|---|---|---|
| K183485 | CryoVizion System | Cryos Technologies Inc. |
| K923792 | Quantec Spinal Measurement System | Quantec Image Processing Ltd. |
| K860225 | Metricom | Far Orthopedics Inc. |
| K851133 | Terran Biomechanical Analysis System | Terran Biomedical Instruments |
| K844736 | ISIS | Oxford Medilog Inc. |
| K800591 | Contourograph M-500 | Bio-Tek Instruments Inc. |

## 3. Indications for Use

The Indications for Use (IFU) statement identifies the condition and patient population for which a device should be appropriately used. The optical contour sensing devices under product code "LDK" cleared in the 510(k)s noted in Table 1 detect postural asymmetries. Representative IFU statements are as follows:

- The device is indicated as a tool to quantify angles on digital photograph depictions such as body angles related to postural asymmetries. It is intended for use in professional health care facilities by health specialists such as podiatrists,

orthopedist, physiotherapists, chiropractors, osteopaths, and kinesiotherapists.

- The device is intended for the detection and monitoring of scoliosis.
- The device is intended for scoliosis, lordosis and kyphosis screening and monitoring.
- The device is intended to provide topographical images to assist in the assessment of postural asymmetries.
- The device is intended for the evaluation of musculoskeletal balance, posture and vertebral curvature.
- The device is intended to measure surface manifestations of the internal parameters of kyphosis, lordosis, and Cobb angle.

# 4. Clinical Background

## 4.1 Disease Characteristics

Spinal deformities encompass scoliosis, kyphosis, and lordosis, and can lead to an imbalance in the structural support of the spine. Scoliosis is defined as a lateral curvature of the spine that is greater than 10 degrees. While kyphosis describes a forward curvature of the thoracic spine beyond the normal range of 30-50 degrees, lordosis describes a backwards curvature of the cervical and lumbar spine when viewed in the sagittal plane. The degrees of curvature are measured by the Cobb angle, which is the most widely used measurement to quantify the magnitude of deformity. The etiology of scoliosis is not well understood but can arise in adolescents idiopathically with genetic factors thought to play a role, and in the adult population as a consequence of degenerative changes in patients with no previous history of scoliosis. Scoliosis may also arise secondary to an underlying medical condition such as osteoporosis, genetic conditions like Marfan syndrome, trauma, paralysis, or following spine surgery.

The prevalence of scoliosis varies within the population. Between 3 to 4% percent of adolescents and 8.3% of adults 25-74 years old have scoliosis. The prevalence of scoliosis associated with degenerative changes increases with age and the rate of occurrence is similar in males and females.

Spinal deformities often present asymptomatically but may also be associated with back and neck pain, postural imbalances causing difficulty with standing or walking, spinal stenosis and neurologic deficits.

Curve progression occurs in 60-70 percent of adults with scoliosis, but the rate of progression is variable. On average, in degenerative lumbar scoliosis in patients over

50, the rate of progression is 3 degrees per year. In adolescent idiopathic scoliosis, curves measuring less than 30 degrees after skeletal maturity typically do not progress, while curves measuring over 50 degrees tend to progress one degree per year. Follow up with an orthopedic surgeon typically occurs until the onset of skeletal maturity and serial radiographs are used to track the progression of Cobb angles.

## 4.2 Diagnosis

The clinical evaluation of a patient with spinal deformities is done with an objective of determining the etiology, and to assess the degree of dysfunction and pain the patient experiences, all three of which inform the management of the condition. The patient history should investigate time of onset, changes in posture, height, the presence and severity of pain, along with screening for "red flag symptoms" suggestive of neurologic injury requiring more urgent evaluation. In addition to a general examination, an examination of the spine includes visual inspection of the spinal curvature, observation of the center of balance and asymmetry of the waist, scapula and shoulders. Physical exam may include specialized tests such as the Adam's forward bend test to characterize the rotational component of scoliosis, and measurement of the asymmetry observed in the thoracic and lumbar regions using a scoliometer, which functions similarly to a leveling tool. Imaging studies include standing anterior-posterior and lateral X-ray views of the spine, which are used to evaluate the etiology of the spinal deformity, determine the magnitude of the curve (Cobb angle), and evaluate the extent of degenerative changes. The diagnosis of scoliosis is confirmed by imaging demonstrating a Cobb angle of >10 degrees of lateral curvature. The Cobb angle can be used to track the severity of scoliosis progression over time. The limitation of standard X-ray imaging is that it does not measure rotational deformity and can have variation in measurement error between 1-5 degrees. Advanced imaging including CT and MRI are indicated in patients with spinal deformity experiencing neurologic symptoms, or when clinical history, physical exam or radiographic findings are suggestive of intraspinal pathology.

## 4.3 Risks

FDA has identified the following risks to health associated with optical contour sensing devices:

**Table 2: Risks to Health and Descriptions/Examples 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. |

| Identified Risk | Description/Examples |
|---|---|
| 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. |

***The Panel will be asked whether this list is a complete and accurate list of the risks to health presented by optical contour sensing devices under product code "LDK" and whether any other risks should be included in the overall risk assessment of the device type.***

# 5. Literature Review

## 5.1 Methods

A systematic literature search was carried out to gather and assess published information regarding the safety and effectiveness of optical contour sensing devices regulated under the LDK product code. Initial online literature searches from 01/01/2010 to 12/31/2020 were performed in two electronic databases (PubMed and Embase) using the following search criteria:

> *device AND (effectiveness OR safety) AND (spinal OR vertebral) AND (scoliosis OR kyphosis OR lordosis OR curvature OR ('posture asymmetry') OR ('postural asymmetry') OR deformity) AND (monitoring OR ('analysis system') OR ('measurement system'))*

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 on a total of 48 publications. However, none of the publications met the inclusion criteria as they were not related to the assessment of the safety or effectiveness of optical contour sensing devices. Therefore, 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 on a total of 6 publication 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 09/01/2020 was conducted, using PubMed and Embase, based on device brand names. A list of FDA-cleared devices is presented in Table 1.

The search term used were as follows: [Brand Name] AND Scoliosis.

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; seven were about Quantec Spinal Measurement System and four about the integrated shape imaging system (ISIS) respectively (one study assessed both devices). Most of the studies were prospectively conducted (6 out of 10), others were retrospective review of medical records (4 out of 10) and there was one meta-analysis. Most of the studies were conducted in the US and UK (8 out of 10). The mean sample size was 111.

**Table 3: FDA Cleared Devices and Articles Found by Device Name**

| 510(k) Number | Trade Name | Sponsor | Number of Relevant Articles |
|---|---|---|---|
| K183485 | CryoVizion System | Cryos Technologies Inc. | 0 |
| K923792 | Quantec Spinal Measurement System | Quantec Image Processing Ltd. | 7 |
| K860225 | Metricom | Far Orthopedics Inc. | 0 |
| K851133 | Terran Biomechanical Analysis System | Terran Biomedical Instruments | 0 |
| K844736 | ISIS (or ISIS2) | Oxford Medilog Inc. | 4 |
| K800591 | Contourograph M-500 | Bio-Tek Instruments Inc. | 0 |

## 5.2 Results

Meta-Analysis

One meta-analysis on topography was identified. (Navarro, Rosa, & Candotti, 2019) In this article the authors intended to (a) identify the anatomical reference markers used on surface topography; (b) identify the parameters used on surface topography; and (c) pool correlation and reproducibility results. Besides optical contour sensing devices, this article also investigated devices that are not cleared under the LDK product code (e.g., BIOMOD™ L system, Formetric 4D system). Among optical contour sensing devices that have been cleared, only the ISIS and Quantec devices were assessed. The author identified 23 studies in order to identify the anatomical markers used by various authors. This article had two subparts, a qualitative discussion and a quantitative analysis. Four (4) articles related to LDK devices were included in this meta-analysis (ISIS: Berryman 2008; Quantec: Liu 2001, Thometz 2000, Klos 2007) but in the quantitative analysis to examine the correlation between the topographical exam and the X-rays, none of the 4 related articles above-mentioned were included. The meta-analysis indicates that the surface topography is

strongly correlated with the X-ray exams, but authors emphasized the lack of standardization in the use of surface topography among the studies, especially in the execution and interpretation of surface topography. The author concluded that the use of surface topography can contribute to the diagnosis and follow-up of the Adolescent Idiopathic Scoliosis (AIS) and recommended the application of a standardized protocol for the use of surface topography, from the proceeding of the examination to the analyses of results.

There are many limitations to this article. This meta-analysis is limited to surface topography, which is only a subset of intended use of optical contour sensing devices. Most of the articles included in the meta-analysis were not related to optical contour sensing devices cleared under the LDK product code. Although this publication concludes that surface topography could achieve similar results as X-ray, which speaks to device effectiveness, no safety conclusions could be drawn.

Quantec Spinal Measurement System

One publication addressed if Quantec can replace X-ray as a standard, stand-alone, scoliosis diagnostic tool (Goldberg, Kaliszer, Moore, Fogarty, & Dowling, 2001). In this study, fifty-nine (59) subjects with both radiograph and topography scans (Quantec) were prospectively followed to determine the ability of topography scan in detecting significant change in Cobb angles. Acknowledging that a significant change in Cobb angle could be identified by associated change in at least one topographic measure in a significant proportion of case, the author concludes that it is unlikely that topography will supplant radiography for the ascertainment of Cobb angles, because the error margins of both are wide, and the two diagnostic methods are not measuring the same aspect of the deformity. Further, the author discusses that the Quantec system can be useful for patient monitoring as an alternative to radiography without diminishing the standard of care. This article provides evidence against using Quantec as a stand-alone scoliosis diagnostic method in terms of effectiveness.

Three articles were published by the same group of researchers from Children's Hospital of Wisconsin, aimed to investigate Quantec as a replacement to X-ray. Although not clearly indicated in the publications, it is possible that the cohorts analyzed in these three publications may partially overlap because all three publications came from the same clinical center and subjects were recruited in roughly the same time period.

The first of the three articles was published in 2000, in which 149 patients with idiopathic scoliosis were evaluated using both the Quantec system and X-ray (Thometz, Lamdan, Liu, & Lyon, 2000). The authors found that the mean difference between the Cobb angle and the Q angle (a coronal plane measurement generated by the Quantec Spinal Imaging System) was 5.7° in the thoracic region, 4.9° in the lumbar region, and 1.7° in the thoracolumbar region. The thoracolumbar region had the least difference between the Q and Cobb angles. Correlation coefficient between Q angle and Cobb angle also was the highest in the thoracolumbar region ($r = 0.70$).

Notably, the difference between the Q and Cobb angles was small when the Cobb angle was <21 degrees with less than 6 degrees of axial surface rotation, which means that Quantec results better mimics X-ray in diagnosing mild scoliosis.

The second article was published in 2001, in which 129 patients with a single curve and 119 patients with a double curve were studied to demonstrate that Quantec could provide functional classification of spinal deformity in patients with mild idiopathic scoliosis without using radiographs. (Liu, Thometz, Lyon, & Klein, 2001) Similar to the previous article, the authors found that the accuracy of classification was relatively high (85%) among patients with mild scoliosis (less than 10 degree in Cobb angle) but decreased in severer cases of scoliosis.

The third article was published in 2007. (Klos, Liu, Lyon, Tassone, & Thometz, 2007) This time, the authors developed a scoliosis diagnostic method called Functional Classification System (FCS) to predict degree of idiopathic scoliosis curvature without radiographs using Quantec. In total, 157 subjects were studies, and the authors found that sensitivity, specificity, and Pearson's correlation coefficient reflect the reliability of the Quantec method. Therefore, they concluded that the FCS method they have developed using Quantec can be considered as a reliable tool for monitoring the progression of scoliosis with reduced need of radiographs.

All three studies supported effectiveness of Quantec as an alternative to X-ray. In terms of safety, the authors emphasized that children with idiopathic scoliosis usually require frequent exposure to radiography and would thus be subject to increased risk of developing cancer. In contrast, Quantec uses quartz halogen light that is not harmful and is suitable for periodic follow-up. In this sense, Quantec has a favorable safety profile and this is widely known in the clinical community.

Another study focused on assessing Quantec’s performance in monitoring the trend of thoracic sagittal curvature in kyphoscoliosis children pre-operatively. (McArdle, Griffiths, Macdonald, & Gibson, 2002) In this study, 57 children were retrospectively investigated, and the author reported that the mean value aligned with expected value. This study demonstrated the value of Quantec in monitoring trend of thoracic sagittal curvature in scoliosis children. This is a very limited conclusion on effectiveness. No safety conclusion could be drawn.

In another study, the authors investigated the ability of Quantec to monitor scoliosis specifically among 20 children with cerebral palsy (Sadani et al., 2012). Validity was assessed by comparing Quantec angle with the gold standard (Cobb angle in X-ray), reproducibility analysis was assessed using Bland-Altman plots, and feasibility was assessed using a questionnaire. The authors found that the mean (and standard deviation) for differences between Cobb and Quantec angle were 0.02° (6.2°) and for Quantec inter-observer variability were 0.5° (5.8°). The authors concluded that Quantec scanning was feasible, reproducible and had good validity when compared with Cobb angle in a supportive seating system. Similar to other articles, this research showed that results comparable to X-ray could be achieved using Quantec.

However, this study only focused on a rather limited patient population (children with cerebral palsy), and the results cannot be considered generalizable.

The literature review showed that the Quantec system was an effective alternative when compared to the standard X-ray. However, as noted in the first research article discussed, the authors recommended against utilizing the Quantec system as a stand-alone scoliosis diagnostic method, but rather as a patient monitoring tool as they concluded that this would not diminish the standard of care. Utilizing the Quantec system as a monitoring device was also recommended in other articles outlined above. However, the literature review did show that the Quantec system, when used as a scoliosis diagnostic tool, was effective at diagnosing mild scoliosis, but this effectiveness decreased as scoliosis severity increased. The aforementioned studies were done in children, so the effectiveness in a broader population was not evaluated making these conclusions limited only to the pediatric population.

ISIS and ISIS2 Device

Most of the articles about this device were published in the late 1980s and early 1990s when ISIS was newly introduced to the US market.

A prospective study followed 34 adolescent female patients with right thoracic idiopathic scoliosis and ISIS results were compared with X-ray results. (Tredwell & Bannon, 1988) Correlation was found only in 50% of the patients. Five patients were predicted to have stayed the same or decreased by ISIS and showed increase on X-ray measurement; eight were predicted to have stayed the same or decreased by X-ray measurement and showed increase by ISIS. In terms of effectiveness, the author concluded that “the clinical usefulness of the ISIS method in following a braced population has not been proven.”

Another study followed 51 patients for 2 years to monitor scoliosis progress, using both X-ray and ISIS. (Weisz, Jefferson, Turner-Smith, Houghton, & Harris, 1988) Cobb angles at the commencement of the study ranged from 10 degrees to 55 degrees. The authors reported that ISIS correctly identified curve evolution in 84% of the patient group and concluded the usefulness of ISIS in assessing scoliosis.

Several excluded studies assessed the ISIS device from the research perspective, and the ISIS device was used for goals other than scoliosis diagnosis, e.g., height measurement, cosmetic measurement, and measuring back shape in non-scoliosis patients. In addition, one study used ISIS to investigate “normal back shape” in young adults as oppose to diagnosing deformity. Although these articles did not directly assess the performance of ISIS in scoliosis diagnosis, it appears that ISIS has been used in different settings and it could indirectly support a favorable safety performance of this product. In early 2000s, a new version (ISIS2) was developed to improve the speed, accuracy, reliability and ease of use of ISIS1. There has been evidence of wide use ever since.

A study in 2008 evaluated the validity of ISIS2 3D back shape measurements for assessment and follow up of patients with scoliosis. (Zubović et al., 2008) A total of 242 patients were followed and 520 ISIS2 scans were performed and the author concluded that ISIS2 scoliosis measurements are "non-invasive, low-cost, three-dimensional topographic back measurements which can be confidently used in scoliosis assessment and monitoring of curve progression." Although this is the only study which directly assessed the validity of ISIS2 in diagnosing scoliosis, several other studies assumed ISIS2 to be a validated tool and have used it to measure spine deformity, which showed that ISIS2 has been recognized among at least some practitioners as a useful tool.

The literature review of the ISIS device as discussed in the first study outlined above showed that it could not be concluded that the ISIS device was effective in monitoring female patients with right thoracic idiopathic scoliosis when compared to the standard X-ray. However, the second study discussed showed that the ISIS device was effective in identifying curve evolution in 84% of the patient population group reviewed when assessing scoliosis progression. Additionally, the ISIS device was shown to be a favorable tool in other assessments outside of scoliosis diagnosis such as investigating normal back shape, and cosmetic measurements, as outlined above.

The literature review also showed that an updated version (ISIS2) of the ISIS device was developed for assessment and follow up of patients with scoliosis. The ISIS2 device was showed to be effective in measuring spine deformities, and was believed to be a validated tool in other studies.

## 5.3 Adverse Events Associated with Optical Contour Sensing Devices

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 this review, it is widely acknowledged that replacing X-ray with optical contour sensing devices for scoliosis diagnosis will lower the exposure to radiation and thus could achieve a favorable safety outcome.

## 5.4 Effectiveness Associated with Optical Contour Sensing Devices

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

## 5.5 Overall Literature Review Conclusions

Overall, the published medical literature evidence 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 exposure to radiation. 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 and the conclusions here are based on publications identified based on brand name specific search that cannot be considered as systematic literature review.

# 6. Risks to Health Identified through Medical Device Reports (MDRs)

## 6.1 Overview of the MDR System

The MDR system provides FDA with information on medical device performance from patients, health care professionals, consumers and mandatory reporters (manufacturers, importers and device user facilities). The FDA receives MDRs of suspected device-associated deaths, serious injuries, and certain malfunctions. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. MDRs 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

Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the submission of incomplete, inaccurate, untimely, unverified, duplicated or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about the frequency of device use. Finally, the existence of an adverse event report does not definitely establish a causal link between the device and the reported event. Because of these limitations, MDRs comprise only one of the FDA's tools for assessing device performance. As such, MDR numbers and data should be taken in the context of the other available scientific information.

## 6.2 MDR Data: Optical Contour Sensing Devices (Product Code LDK)

Individual MDRs for optical contour sensing devices are reported through FDA's Manufacturer and User Facility Device Experience (MAUDE) Database, which houses mandatory reports from medical device manufacturers, importers and user facilities, as well as voluntary reports from entities such as health care professionals, patients and consumers.

The Agency searched the MDR database on March 9, 2021 and repeated on September 3, 2020 to identify adverse events related to the use of optical contour

sensing devices (Product Code LDK) entered between April 1, 1980 and December 31, 2020. The search did not identify any relevant MDRs for optical contour sensing devices.

# 7. Recall History

## 7.1 Overview of Recall Database

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 may occur after the firm recalling the medical device product conducts and communicates with its customers about the recall. Therefore, the recall information posting date ("create date") identified on the database indicates the date FDA classified the recall, it does not necessarily mean that the recall is new.

## 7.2 Recall Results: Optical Contour Sensing Devices

The FDA conducted queries of the Medical Device Recall database on March 9, 2021, to identify recalls related to optical contour sensing devices (product code LDK). The search was not timeframe restricted and included all recalls reported under product code LDK. The search did not identify any relevant recalls for optical contour sensing devices.

# 8. Summary

In light of the information available, the Panel will be asked to comment on whether optical contour sensing devices under product code “LDK”:

meet the statutory definition of a Class III device:

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

or would be more appropriately regulated as Class II, in which:

- general and special controls, which may include: performance standards, postmarket surveillance, patient registries and/or development of guidelines, are sufficient to provide reasonable assurance of safety and effectiveness

or as Class I, in which:

- the device is subject only to general controls, which include: registration and listing, good manufacturing practices (GMPs), prohibition against adulteration and misbranding, and labeling devices according to FDA regulations.

For the purposes of classification, FDA considers the following items, among other relevant factors, as outlined in 21 CFR 860.7(b):

1. The persons for whose use of the device is represented or intended;
2. The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;
3. The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and
4. The reliability of the device.

## 8.1 Special Controls

For optical contour sensing devices with the intended use to measure various anatomical landmarks for medical purposes, and to detect abnormalities such as postural asymmetries, FDA does not believe that special controls will be required and that general controls will be sufficient to provide a reasonable assurance of the safety and effectiveness.

## 8.2 Overview of Proposed Classification/FDA Recommendation

Based on the safety and effectiveness information gathered by the FDA, the identified risks to health and recommended mitigation measures, we recommend that optical contour sensing devices indicated for use to measure various anatomical landmarks for medical purposes, and to detect abnormalities associated with postural asymmetries be regulated as Class I devices.

**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). The device is exempt from the premarket notification procedures in subpart E of Part 807 of this chapter, subject to limitations in 890.9.

***Based on the available scientific evidence, the FDA will ask the Panel for their recommendation on the appropriate classification of optical contour sensing devices under product code "LDK."***

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**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.**