24 Hour Summary
General and Plastic Surgery Devices
Advisory Committee Meeting
July 29, 2022

Introduction:

On July 29, 2022, FDA conducted a Public Advisory Committee meeting to discuss the possible reclassification of approved computer-aided melanoma detection class III devices: (1) MelaFind, a device that uses multispectral imaging and was approved in 2012 (P090012; https://www.accessdata.fda.gov/script..., and (2) Nevisense, a device that measures impedance and was approved in 2017 (P150046; https://www.accessdata.fda.gov/script...). The committee discussed if there is sufficient information to reclassify computer-aided devices for adjunctive diagnostic information of lesions suspicious for melanoma from class III to class II, and what special controls may be appropriate to provide reasonable assurance of safety and effectiveness for these devices if they are reclassified as class II devices.

Device Description:

Both Melafind and Nevisense devices are intended for use on cutaneous lesions suspicious for melanoma when a dermatologist chooses to obtain additional information when considering biopsy.

Panel Deliberations/FDA Questions:

The discussion focused on classification recommendations for Optical Diagnostic Devices for Melanoma Detection and Electrical Impedance Spectrometers, which are currently regulated as Class III devices. To provide context and background for the deliberations and FDA questions, FDA presented on device classes and how they are defined, current FDA-approved computer-aided devices for skin lesions suspicious for melanoma, post-market safety and effectiveness, device classification and reclassification, and proposed reclassification and regulatory controls.

The General and Plastic Surgery Devices Advisory Panel (the Panel) discussed and made recommendations on FDA questions related to the reclassification of SLAs. The Panel discussed the completeness and accuracy of the risks to health for computer-aided devices which provide adjunctive diagnostic information to dermatologists about lesions suspicious for melanoma provide by FDA. The Panel agreed with inclusion of the risks identified by FDA, but suggested additional risks be included, such as device bias in different populations,

phycological impact of false positives and false negatives, risks associated with specific locations of device use and interference with implants, risks associated with inadequate user training, and risks associated with algorithm performance drift in real-world use, etc. The Panel also discussed the proposed Class II device criteria for computer-aided devices which provide adjunctive diagnostic information to dermatologists about lesions suspicious for melanoma: the sufficiency of general controls for safety and effectiveness, assessments for the impairment of human health, risk of illness or injury, and the sufficiency of existing information to establish special controls for this device type. The Panel agreed that general controls alone are not sufficient to provide a reasonable assurance of safety and effectiveness for this device type. The panel had varying opinions in identifying the devices as "life supporting or life-sustaining, or of substantial importance in preventing impairment of human health" and whether or not these devices present a "potential unreasonable risk of illness or injury", with consideration of the adjunct use nature of the device, and the high risks of false negatives. Regarding existing information to establish controls for the device type, some panel members agreed that sufficient information exists to establish special controls for this device type, and others of the panel disagreed, suggesting more information is needed to understand the device performance and its benefits and risks in real-world use, and it may be overly burdensome and not feasible to set special controls to mitigate all the risks associated with the device type. Lastly, the Panel discussed whether the proposed special controls appropriately mitigate the identified health risks of this device type. The Panel was also asked to make recommendations for additional or different special controls where applicable. Several of the panel members believe that this device type should not be down classified, and the proposed special controls are needed but not sufficient. The panel recommended additional measures of risk mitigation or control, such as post-approval study and surveillance, metrics to evaluate patient benefits and risks in addition to sensitivity and specificity, in specific patient populations and subtypes, prospective real-world use studies, consideration of patient reported outcome, etc.

Open Public Hearing (OPH)

The Panel heard presentations from clinicians and other stakeholders. Mr. Simon Grant, CEO of SciBase AB (a manufacturer of Nevisense (P150046)) emphasized the high-risk nature of this device type and the need for Class III regulation. Mr. James Castro Argueta, medical student at George Washington School of Medicine and Health Sciences speaking on behalf of the National Center for Health Research (NCHR), discussed the concerns the NCHR has with the proposed reclassification of SLA devices. Lastly, Dr. Lily Peng, speaking on behalf of Google Health, presented the consumer's perspective as it relates to skin issues.

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Transcripts:

Transcripts may be downloaded from:
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OR

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