

# **24 Hour Summary General and Plastic Surgery Devices Advisory Committee Meeting July 28, 2022**

## **Introduction:**

On July 28, 2022, FDA conducted a Public Advisory Committee meeting to discuss the topic of skin lesion analyzer technology and its application to detecting skin cancers in various patient care settings. The Committee was asked to discuss and provide recommendations regarding:

- The diagnosing standard, or ground truth, based on factual data that should be used as a comparison for the performance of diagnostic devices including, but not limited to, histology, consensus opinion of a panel of dermatologists, opinion of a single dermatologist, or other means.
- Acceptable thresholds for sensitivity and specificity based on the target diagnosis (melanoma, basal cell carcinoma (BCC), squamous cell carcinoma (SCC)), or on the intended user (dermatologist, primary care physician, lay user) if assessed for standalone performance.
- Patient characteristics, including lower or higher incidence populations, that should be tested before marketing.
- The balance of increased access with risk mitigation measures that are appropriate when the devices are used by lay people, by populations with very high or very low incidence of melanoma, by populations with low incidence, but high mortality associated with melanoma, or by the target diagnosis/lesion type (melanoma, BCC, SCC).

## **Device Description:**

Skin lesion analyzer devices are algorithm-based devices for adjunctive detection of various skin lesions, including skin cancers. These computer algorithm-aided devices for adjunctive detection of lesions suspicious for skin cancers are referred to as Skin Lesion Analyzers (SLAs).

## **Panel Deliberations/FDA Questions:**

The discussion focused on currently available scientific and clinical data pertaining to the diagnosing standard also known as ground truth, performance criteria, and patient population in future studies assisting medical providers in properly identifying skin lesions by a computer algorithm-aided device. To provide context and background for the deliberations, FDA presented on the Agency's current oversight of SLA devices: an overview of skin lesions, the SLA landscape, special considerations (diagnostic accuracy and ground truth), and the benefit/risk and prevalence considerations. To conclude the morning presentations, the General and Plastic Surgery Devices Advisory Panel (the Panel) heard from two invited speakers. Dr. Glenn I. Cohen presented on the topics of bias and health equity as they relate to Artificial Intelligence (AI) and Machine Learning (ML). Dr. Adewole S. Adamson presented on health disparities in skin cancer prevention in the age of AI.

In the afternoon, the Panel deliberated and made recommendations on FDA questions related to SLAs. The Panel discussed the importance of using histopathology for obtaining ground truth diagnosis in skin lesions in SLA clinical trials and whether alternate means or a combination of ground truth is acceptable in such trials. The Panel generally believed histological diagnosis is required. There was some advocacy for alternative approaches depending on lesion type, the intended use of the device, the user or clinical setting, the patient population, the specific study design. The Panel also discussed the FDA-proposed performance thresholds for sensitivity and specificity for melanoma, Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC) for SLA devices intended for both adjunctive and standalone use. The panel recommended additional evaluation endpoints besides the binary sensitivity and specificity metric. The Panel was in favor of a performance threshold that shows the device improves the performance of the clinical user or improves the patient benefit, which may depend on the particular use condition, e.g., different cancer types or different healthcare users, with certain level of safety assurance. The Panel highlighted the importance of prospective data from real-world use and post-market studies or surveillance to monitor real-world performance over time. The Panel discussed the impact of false negative and false positives for different cancer types, in different use scenarios especially for lay users. The Panel agreed that the risks of false negatives are very high, while the cost and psychological impact of false positives should also be evaluated for a balanced analysis to inform the selection of performance thresholds. The sensitivity and specificity threshold should be higher for stand-alone devices compared to devices for adjunct use. Lastly, the Panel discussed the allowance of SLA devices to be marketed despite limited testing in low-prevalence populations. The Panel agreed that all skin types should be studied, but allowances can be given to some devices to market the device for tested population before adequate data are collected from all populations. Other strategies or measures can be used to promote or enforce continuing data collection in low incidence population, such as post-approval study requirements, requirement of transparency in prevalence data.

## **Open Public Hearing (OPH)**

The Panel heard presentations from clinicians and other stakeholders. Dr. William Steffes, a Board-Certified Dermatologist speaking on behalf of SciBase AB (a manufacturer of Nevisense (P150046)), discussed the risks associated with the use of SLA devices Mr. Simon

Grant, CEO of SciBase AB (a manufacturer of Nevisense (P150046)), presented on the importance of considering patient risks and adequate regulation of SLA devices.

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**Transcripts:**

Transcripts may be downloaded from:

[July 28-29, 2022: General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee Meeting Announcement - 07/28/2022 | FDA](#)

OR

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