Published FDA Pivotal Studies Find DermaSensor has 96% Sensitivity and Cuts Physicians' Missed Skin Cancers by Half

MIAMI, FL, UNITED STATES, June 12, 2025 /EINPresswire.com/ -- Published in the Journal of Primary Care and Community Health, the joint FDA pivotal studies demonstrated the performance and benefits of the hand-held, non-invasive, optical spectroscopy device in point-of-care skin lesion evaluation.

In collaboration with faculty from Mayo Clinic, Yale University, the University of North Carolina School of Medicine, and SUNY Downstate Health Sciences University, announced the publication of two pivotal studies validating the company's novel Elastic Scattering Spectroscopy (ESS) device for skin cancer detection in primary care. One study assessed the standalone performance of the ESS device, while the second evaluated how device use impacted primary care physicians (PCPs) skin cancer detection and management.

In the multicenter validation study, led by Mayo Clinic, 1,005 patients and 1,579 lesions were evaluated across 22 primary care sites. Dermatopathologic analysis confirmed 224 skin cancers, including melanomas, basal cell carcinomas, and squamous cell carcinomas. The ESS device was found to have a skin cancer detection rate, or sensitivity, of 96%[1]. This performance level compared favorably to the 90% target based on dermatologists' sensitivity in the literature, which is also the FDA's minimum required sensitivity for melanoma. For negative device results, the likelihood that a lesion was benign (i.e. negative predictive value (NPV)) was 97%. For positive

results, the likelihood a lesion was cancerous (i.e. positive predictive value (PPV)) ranged from 6% for the lowest score of 1 to 61% for the highest score of 10.

“The DermaSensor device is an easy-to-use, point-of-care, hand-held skin cancer assessment device with high sensitivity and NPV for use in the primary care setting. Use of the device can help inform PCP decision-making about skin lesions suspicious for cancer, which need further evaluation and those that may be monitored,” wrote Stephen Merry, MD, MPH, from Mayo Clinic in the abstract as lead author of the pivotal trial.

The companion clinical utility study with 108 physicians found that use of the ESS device significantly enhanced physicians' ability to identify and correctly refer skin cancers and improved their overall skin lesion management accuracy. PCPs correctly referred 91.4% of malignant lesions when aided by the device, compared to just 82.0% without it—a 50% reduction in missed cancer referrals (from 18.0% to 8.6%)[2].

“I have spent most of my career researching and using skin cancer diagnostic tools. It has been a long-time unaddressed goal of the dermatology and primary care communities to have an easy-to-use tool that can provide an automated risk assessment for suspicious lesions.” said Laura Ferris, MD PhD, who is the Chair of Dermatology at UNC Chapel Hill, the lead author of this utility study, and a leading researcher on skin cancer diagnostic tools. “Now that DermaSensor is the first such tool available for PCPs and, given the clear device benefits that our study and others have demonstrated, I am optimistic for the impact this device will have on skin cancer detection and care.”

Skin cancer remains the most common cancer globally, accounting for more cases annually than all other cancers combined[3]. While many deadly skin cancer cases are preventable through sun protection and early detection, delayed diagnosis continues to drive unnecessary mortality, morbidity and high healthcare expenses.

“These two FDA pivotal studies – the main clinical studies of the six submitted to FDA – highlight the strong performance and benefits of our device, which were instrumental in DermaSensor becoming the first FDA-authorized tool in the US that provides anyone with any kind of objective risk assessment for melanoma, BCC and SCC.” said Cody Simmons, Co-Founder and CEO of DermaSensor. “Since receiving FDA De Novo clearance of this FDA Breakthrough Device last year, there are already hundreds of diverse doctors using our devices, and we are working to quickly scale device adoption so that our device can benefit many of the millions of patients that are diagnosed with skin cancer each year.”

About DermaSensor Inc.

DermaSensor Inc. is a Miami-based medical device company that enables healthcare professionals to effectively check for skin cancer by leveraging cutting-edge technologies. The DermaSensor™ device is a cost-effective handheld tool that uses artificial intelligence and

spectroscopy to non-invasively test skin lesions for skin cancer risk in seconds. By enabling quick and effective skin cancer checks, DermaSensor ultimately hopes to improve skin cancer detection and save lives. DermaSensor is currently FDA Cleared, CE Marked, and is available for sale in the U.S.

References:
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2. Ferris LK, Jaklitsch E, Seiverling EV, et al. DERM-SUCCESS FDA Pivotal Study: A Multi-Reader Multi-Case Evaluation of Primary Care Physicians' Skin Cancer Detection Using AI-Enabled Elastic Scattering Spectroscopy. Journal of Primary Care & Community Health. 2025;16. doi:10.1177/21501319251342106
3. https://www.skincancer.org/skin-cancer-information/skin-cancer-facts/ accessed on June 6, 2025.

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