Nature declares that FDA's clearance of DermaSensor "marks a pivotal moment in digital health innovation"

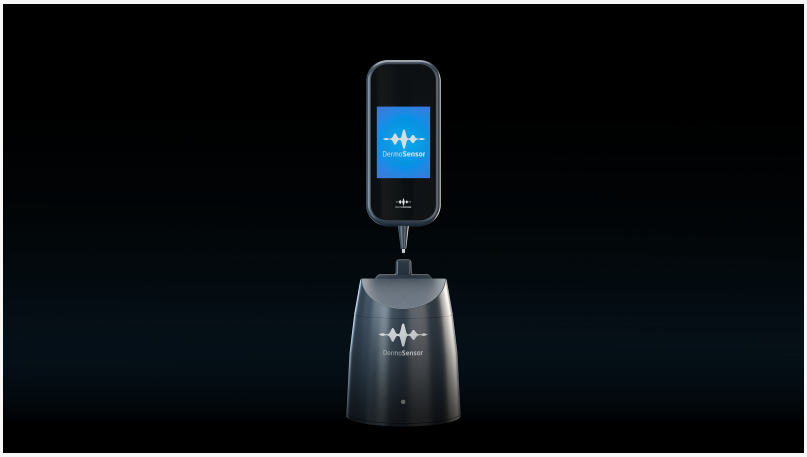
The new article from Nature describes the critical role of DermaSensor in bringing improved diagnostic capabilities into primary care settings.

MIAMI, FLORIDA, UNITED STATES, July 1, 2024 /EINPresswire.com/ -- A recently published Nature[1] article describes how skin care could be undergoing a significant transformation with the introduction of the AI-powered device DermaSensor. Traditionally, dermatological diagnosis has relied highly on visual assessment, with dermatologists differentiating between "normal" and "abnormal" skin lesions based on years of pattern recognition training. This reliance poses a challenge for non-specialists and creates an opportunity for AI/ML (artificial intelligence/machine learning) innovations. The three most common skin cancers are squamous cell carcinoma, basal cell carcinoma, and melanoma, with initial evaluations typically performed through gross assessment and dermatoscopy before confirming diagnosis via biopsy or excision. Primary care physicians (PCPs) often conduct preliminary exams, referring lesions to dermatologists. The NPJ article[1] "Learnings from the first AI-enabled skin cancer device for primary care authorized by FDA," part of Nature's portfolio of journals, describes the critical role of DermaSensor in bringing improved diagnostic capabilities into primary care settings, thus enhancing the broader healthcare system.

> DermaSensor has finally addressed the long-standing need to help all physicians best decide what to do when a patient asks them 'what do you think about this odd-looking mole?'"
>
> *Cody Simmons, DermaSensor CEO*

The article[1] reviews how the first automated skin lesion device to receive FDA authorization was MelaFind (multispectral imaging) in 2011 via the PMA pathway. However, MelaFind was limited in use to dermatologists and to only detect melanoma, and it was discontinued due to

low specificity (10%), high cost, narrow use cases, and poor workflow integration[2]. Nevisense (electrical impedance spectroscopy) also received PMA authorization in 2017 but only for dermatologists to only detect melanoma, and it too has little adoption[3].



“Not only has our device been found to decrease PCPs’ missed skin cancers by half and increase their overall accuracy, but the device is handheld, automated, non-invasive and it’s effective for all three skin cancer types. We just started shipping devices to customers in May, and over 100 physicians are already been trained on use of our device. After a decade of R&D, it is an honor to now begin transforming skin care in America," said Cody Simmons, Co-Founder and CEO of DermaSensor.

DermaSensor's FDA authorization via the De Novo pathway, targeted at physicians who are not already specialists in skin lesion diagnosis, is supported by robust clinical evidence. The company’s FDA submission included six clinical studies and two non-clinical studies. Key studies and findings include:

DERM-SUCCESS Pivotal Study[4]: Conducted on 1,579 lesions from 1,005 patients across 22 primary care centers, the study demonstrated a 95.5% device sensitivity which was superior to PCPs’ sensitivity of 83.0% and non-inferior to dermatologists’ sensitivity in literature. The device’s negative predictive value (NPV) was 96.6% and its positive predictive value (PPV) was 39.6% for results between 8-10 .

DERM-ASSESS Supplemental Validation Study[4]: Evaluated 440 lesions from 311 patients, finding that the device's sensitivity and accuracy (i.e. AUROC) was on par with in-person dermatologists. The device NPV for melanoma was 98.1%, with melanoma PPV of 47.4% for results between 8-10.

Clinical Utility Study[4]: Involved 108 PCPs and over 10,000 lesions, indicating increased referral and diagnostic sensitivity with reduced false negative referrals and higher overall accuracy (i.e. AUROC).

Future Directions and Health Equity Considerations

The article[1] describes that, “DermaSensor provides new horizons for dermatologic care by extending the diagnostic capacity of primary care physicians (PCPs) for skin cancer. This is a key differentiator from previous FDA-authorized AI-enabled medical devices in dermatology. The use

of DermaSensor could strengthen the diagnostic abilities of PCPs who normally refer to such cases, potentially addressing access limitations in dermatology. It is estimated that more than a third of patients face access limitations[5]". DermaSensor not only enhances the performance of non-specialist physicians but could also help better prioritize high-risk patient referrals to dermatology.

The FDA's health equity-focused regulatory approach for this new category of device ensures that diverse patient populations are tracked through post-market surveillance, potentially shaping future regulatory standards. The article[1] states "while the short-term impact of DermaSensor's authorization is the addition of a new AI-enabled specialty tool in the primary care toolkit, the device's long-term legacy may be a milestone for the regulation of AI-enabled medical devices."

For more information about DermaSensor and its transformative skin cancer detection solution, please visit www.dermasensor.com.

About DermaSensor

DermaSensor Inc. is a health technology company designing non-invasive tools to better equip primary care physicians for skin cancer detection. The DermaSensor device is an affordable, handheld tool that uses spectroscopy and algorithms to evaluate skin lesions for potential cancer in a matter of seconds. DermaSensor is currently FDA-Cleared, CE-Marked, and is available for sale in the U.S.

References:

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