

Research strategy DermaSensor

FDA approval (510k)

Studies

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Summary

This document summarizes the preclinical and clinical investigations carried out by DermaSensor, which we intend to follow in our FDA approval process.

DermaSensor has carried out 10 different studies to provide data regarding the effectiveness and safety of the device. 4 of these studies (tagged as “Early Clinical Effectiveness Studies”) used portions of their datasets in algorithm training, were conducted using a different device result structure or included lesions other than those solely suggestive of skin cancer to physicians. These preclinical studies are summarized in the table below.

Early Clinical studies (Preclinical)

Study Name	Characteristics & design	Sample size and characteristics	Analysis type
DermaSensor Use in the Assessment of Skin Lesions Suggestive of Cancer (DERM-ASSESS II)	US-based, multicenter, prospective, blinded study at 4 dermatology sites.	333 lesions (169 malignant, 164 benign)	Patients: Lesions were evaluated on patients.
Use of an ESS-based Adjunctive Tool in the Assessment of Lesions Suggestive of Skin Cancer (Skin Center	Single-site, prospective, blinded study at one dermatology site in New Zealand	410 lesions (50 malignant, 360 benign)	Patients: Lesions were evaluated on patients.

Study Name	Characteristics & design	Sample size and characteristics	Analysis type
Investigator-Initiated Study (IIS))			
Use of DermaSensor on Patient-Selected Lesions that are Concerning for Skin Cancer (PATIENT-SELECT)	US-based prospective, blinded study at one primary care site involving patient-selected lesions	155 lesions (10 malignant, 145 benign).	Patients: Lesions were evaluated on patients.
A Multi-Reader Multi-Case Companion Study to the DERM-ASSESS II Clinical Study (DA-II Reader Study)	US-based prospective Multi-Reader Multi-Case (MRMC) companion study to DERM-ASSESS II.	57 Primary Care Physicians (PCPs) completed 5,700 assessments.	Images: Physicians analyzed case data from the clinical study

Major Clinical Study and Multi-Reader Multi-Case (MRMC) Studies

This section covers the pivotal validation of the current device and algorithm. It includes the major clinical study (**DERM-SUCCESS**) where the device was used on patients, and three MRMC studies where physicians assessed lesion case data (images and clinical info) to measure the impact of the device's results on their referral decisions.

Study Name	Characteristics & design	Sample size and characteristics	Analysis type	Effectiveness results
DERM-SUCCESS <i>(Major Clinical Study)</i>	International, multicenter, prospective, blinded study at 22 primary care sites (18 US, 4 Australia).	30 PCPs enrolled 1,005 subjects with 1,579 lesions (224 malignant)	Patients: PCPs assessed live patients and biopsied lesions (2 to 5 dermatopathologists).	<ul style="list-style-type: none"> • Device Sensitivity: 95.5%, superior to PCP sensitivity of 83.0% ($p < 0.0001$). • Odds Ratio: 4.93 ($p < 0.0001$). • Specificity:

Study Name	Characteristics & design	Sample size and characteristics	Analysis type	Effectiveness results
				20.7%.
Pivotal Reader Study <i>(MRMC Companion)</i>	US-based prospective MRMC study.	108 board-certified PCPs completed 10,800 assessments.	Images: Physicians evaluated 50 case files (25 malignant, 25 benign).	<ul style="list-style-type: none"> • PCP Sensitivity: Improved from 82.0% (unaided) to 91.4% (aided) (p=0.0027) . • Odds Ratio: 6.8 (p<0.0001) . • Accuracy (AUROC): Increased from 0.708 to 0.76.
Pigmented Reader Study <i>(MRMC Study)</i>	US-based prospective MRMC study for pigmented lesions	77 board-certified PCPs completed 10,472 assessments.	Images: Physicians evaluated 136 pigmented lesion cases (69 malignant).	<ul style="list-style-type: none"> • Aided PCP Sensitivity: Increased 5.8% (superiority, p<0.001) . • Melanoma Sensitivity: Increased 6.6% (superiority, p=0.029) . • Specificity: Decreased 10.6% (non-inferiority)
DERM-ASSESS III Reader Study <i>(MRMC Study)</i>	US-based prospective MRMC study for lesions suggestive of melanoma.	118 board-certified PCPs completed 11,800 assessments.	Images: Physicians evaluated 100 lesion cases (50 malignant).	<ul style="list-style-type: none"> • Aided PCP Sensitivity: Increased 8.1% (superiority, p<0.001) . • Melanoma

Study Name	Characteristics & design	Sample size and characteristics	Analysis type	Effectiveness results
				Sensitivity: Increased 8.8% (superiority, p<0.001) . • AUROC: Increased 4.1% (p=0.036).

Minor Clinical studies

These two studies focused on specific performance metrics in dermatology settings and device reliability.

- **DERM-ASSESS III (Melanoma Study):** This was an international, multicenter, prospective, blinded study conducted at 10 dermatology sites (8 US, 2 Australia) involving **311 subjects** and **440 lesions**. Its goal was to evaluate performance on lesions specifically suggestive of melanoma in a high-prevalence setting.
 - **Results:** The device achieved **90.9% sensitivity** for high-risk lesions and **95.5% sensitivity** for melanoma specifically. Specificity was 32.5%.
- **DERM R and R (Repeatability and Reproducibility):** This study was conducted at two sites (one in the US and one in Australia) with 52 subjects and 64 lesions to validate the consistency of the results.
 - **Results:** The study showed high agreement rates. **Repeatability** (agreement between scans on the same device) was **84.2%**, and **Reproducibility** (agreement between different devices/physicians) was **87.8%**. For malignant lesions specifically, agreement was even higher at **97.1%** for both repeatability and reproducibility.