

FDA authorises DermaSensor, an AI skin cancer checker for primary care doctors

Source copy kept by wheresthe.ai for the story "FDA authorises DermaSensor, an AI skin cancer checker for primary care doctors" (<https://wheresthe.ai/d/us-fda-dermasensor-de-novo-2024-01/>).

Source: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN230008>

Text saved 18 Oct 2026 (the page as published).

SHA-256 of the saved text: 8eeb55352435d3e5d40927a74839d1ffdf285baf88cc3fda042e314e229a63b3

Documents the source offers: https://www.accessdata.fda.gov/cdrh_docs/pdf23/DEN230008.pdf; http://www.accessdata.fda.gov/cdrh_docs/reviews/DEN230008.pdf

Device Classification Under Section 513(f)(2)(De Novo)

Quick Links: [Skip to main page content](#)

[Skip to Search](#)

[Skip to Topics Menu](#)

[Skip to Common Links](#)

[U.S. Food & Drug Administration](#)

[Follow FDA](#)

[En Español](#)

[Search FDA](#)

[Home](#)

[Food](#)

[Drugs](#)

[Medical Devices](#)

[Radiation-Emitting Products](#)

[Vaccines, Blood & Biologics](#)

[Animal & Veterinary](#)

[Cosmetics](#)

[Tobacco Products](#)

Device Classification Under Section 513(f)(2)(De Novo)

[FDA Home](#)

[Medical Devices](#)

[Databases](#)

-

[510\(k\)](#) | [DeNovo](#) | [Registration & Listing](#) | [Adverse Events](#) | [Recalls](#) | [PMA](#) | [HDE](#) | [Classification](#) | [Standards](#)

[CFR Title 21](#) | [Radiation-Emitting Products](#) | [X-Ray Assembler](#) | [Medsun Reports](#) | [CLIA](#) | [TPLC](#)

[New Search](#) [Back to Search Results](#)

Device Classification Name

software-aided adjunctive diagnostic device for use by physicians on lesions suspicious for skin cancer

De Novo Number DEN230008

Device Name DermaSensor

Requester

dermasensor, inc.

80 sw 8th st. #2000

miami, FL 33130

Contact cody simmons

Regulation Number 878.1830

Classification Product Code

QZS

Date Received 02/02/2023

Decision Date 01/12/2024

Decision

granted

(DENG)

Classification Advisory Committee

General & Plastic Surgery

Review Advisory Committee

General & Plastic Surgery

Classification Order

Classification Order

FDA Review Decision Summary

Type Direct

Predetermined Change Control Plan Authorized No

-

-

This website has been translated to Spanish from English, and is updated often. It is possible that some links will connect you to content only available in English or some of the words on the page will appear in English until translation has been completed (usually within 24 hours). We appreciate your patience with the translation process. In the case of any discrepancy in meaning, the English version is considered official. Thank you for visiting esp.fda.gov/tabaco.

-->

Links on this page:

Page Last Updated: 10/12/2026

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#) .

Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility

Contact FDA

Careers

FDA Basics

FOIA

No FEAR Act

Nondiscrimination

Website Policies / Privacy

U.S. Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, MD 20993

Ph. 1-888-INFO-FDA (1-888-463-6332)

Contact FDA

For Government

For Press

Combination Products

Advisory Committees

Science & Research

Regulatory Information

Safety

Emergency Preparedness

International Programs

News & Events

Training and Continuing Education

Inspections/Compliance

State & Local Officials

Consumers

Industry

Health Professionals

FDA Archive

Vulnerability Disclosure Policy

Links on this page: