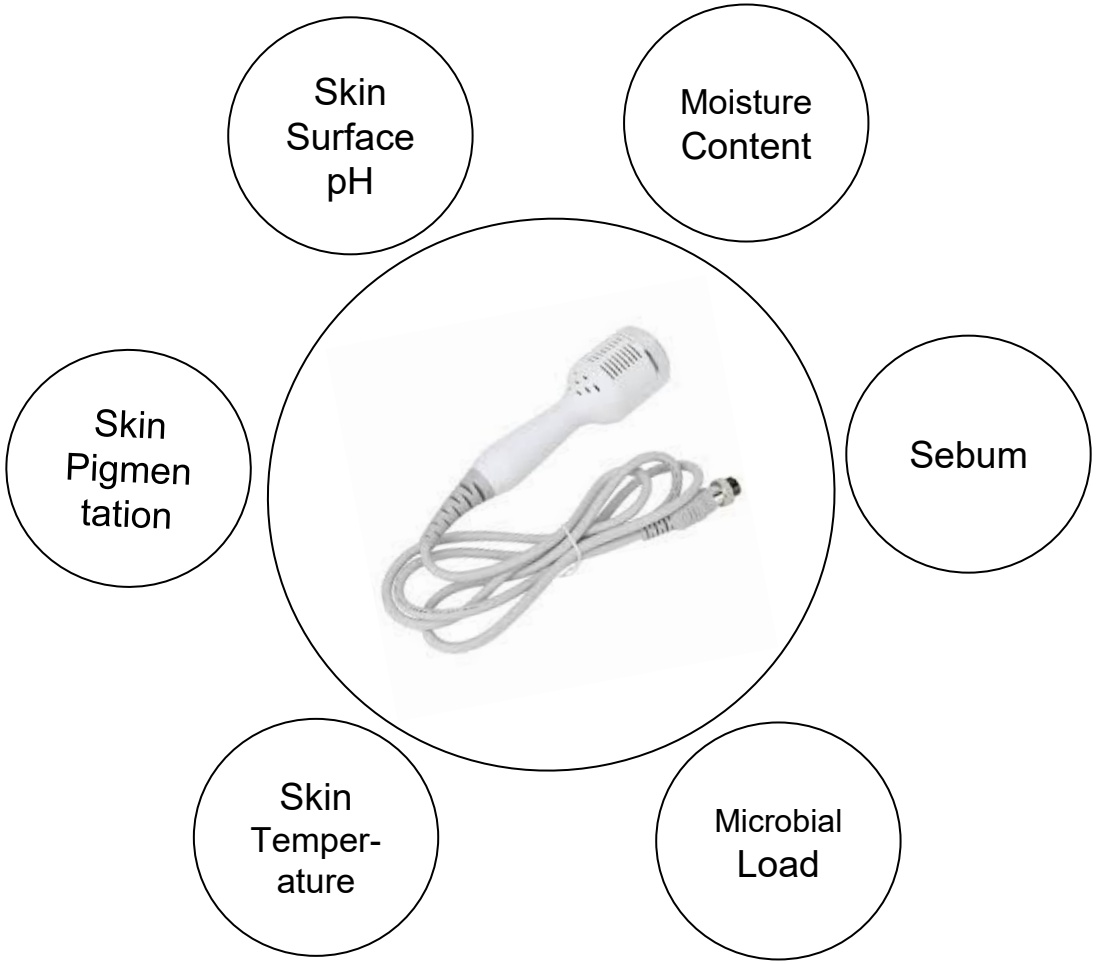
DermaScan Project Proposal



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Date: Aug 18, 2025

Note: This presentation does not contain any confidential information. All numbers are placeholders and do not represent actual values.

Product Snapshot – Strategy & General Market

Description (High level summary of product/initiative)

- DermaScan is a non-invasive, multi-sensor skin analysis system that measures hydration, pH, sebum, pigmentation, temperature, and microbial load.
- It provides quantitative, objective data to support dermatology, cosmetic research, and personalized skincare solutions.

Strategic Fit / Intent (Why are we doing this? What about this product will achieve that?)

- Addresses rising demand for evidence-based skincare and personalized dermatology.
- Enhances credibility of skincare product claims through objective measurement tools.
- Supports company vision to integrate health, beauty, and AI-driven insights.

Value Proposition

- First-in-class multi-parameter probe replacing several single-function analyzers.
- Delivers real-time, accurate, and reproducible data.
- Bridges clinical dermatology and consumer skincare markets.
- Enables data-driven product recommendations (skincare + supplements)

Long-Term Plan for this NPI (What other initiatives etc. will this NPI lead to in the future?)

- Expand to home-use models for consumer wellness monitoring.
- Integrate with DermaDiet and DermaSkin platforms for a full personalized health ecosystem.
- Future applications in clinical trials, tele-dermatology, and AI-based skin health tracking.

Market Size (Addressable market if possible)

- Global skin analysis & diagnostic devices market estimated at $2.5B+ by 2028, CAGR ~12%.
- Growth driven by cosmetics, wellness, and digital dermatology trends.
- Target segments: professional dermatology clinics, cosmetic companies, wellness centers, and premium consumer markets.

Comments:

Target Customer Segments & Description (Also list key purchasing drivers)

- Dermatologists & Clinics: Need objective assessment tools for treatment monitoring.
- Cosmetic & Skincare Brands: Support efficacy claims with validated skin data.
- Research & Academia: Non-invasive tool for clinical studies.
- Consumers (Phase 2): Personalized skincare and wellness guidance.

Main Competitors

- Courage+Khazaka (Corneometer, Sebumeter, Mexameter).
- CK Electronic (Skicon hydration analyzer).
- Aramo & BioMetrix (consumer-facing skin analyzers).

Competitive Positioning (E.g., attributes we excel at, do worse at, or are on par w/ competitors)

- Strengths: Multi-analyte integration, AI-driven reporting, user-friendly app, interoperability with supplements/cosmetics.
- Differentiators: First holistic skin health platform combining hardware + software + ecosystem.

Product Snapshot – Detailed Features and Risks

Key Technical Attributes & Features	Technical Risks
• Multi-sensor handheld probe (hydration, pH, sebum, pigmentation, temperature, microbial load). • AI-powered mobile app for real-time visualization & data storage. • Cloud connectivity for longitudinal tracking & integration with wellness platforms. • User-friendly interface designed with human factors principles (ISO 62366).	• Sensor calibration drift over time. • Variability in skin readings due to environment (humidity, lighting, temperature). • Data accuracy dependent on skin type and tone diversity. • Integration risks between hardware sensors and mobile app.
Useful Features NOT Included (List other features that could make this product more successful)	**Market Risks**
• Direct diagnostic capability (to avoid higher regulatory class). • Imaging-based lesion detection (beyond scope of initial launch). • Consumer self-use model (planned for later version).	• Regulatory reclassification (IVDR Class C, FDA PMA risk). • Competitive response from established players (Courage+Khazaka, Aramo). • Clinician adoption barriers if perceived as cosmetic-only tool. • Consumer skepticism if results not well validated.
Planned Launch Regions, Regulatory Clearances	**Dependencies with Non-Software Products**
• U.S. FDA 510(k) – Class II submission. • EU MDR CE Mark – Class IIa. • Expansion to Canada, Japan, Brazil after initial clearance.	• Biocompatible probe materials (ISO 10993 compliance). • Disposable probe tips / covers (infection control). • Calibration standards and reference devices for validation.
Bioinformatics requirements for designing this product	**Software requirements for final solution** (E.g., new analysis tools, SW connectivity)
- Database of normative skin parameter values across age, ethnicity, and geography. - Algorithm development for trend analysis and anomaly detection. - Secure anonymized data storage for regulatory and clinical validation.	- Embedded firmware for sensor control and data acquisition. - Mobile app with HIPAA/GDPR-compliant data handling. - Cloud backend for storage, analytics, and report generation. - Cybersecurity safeguards (FDA Cybersecurity guidance, IEC 81001-5-1).

Intended Use – Sensor Type and Integration Notes

Parameter	Reference Range	Low Value Implications	High Value Implications	Sensor Type / Method	Integration Notes
Skin Surface pH	pH 4.5–5.5	Barrier dysfunction, irritation, susceptibility to infection	Pathogen overgrowth, acne, inflammation	ISFET or potentiometric pH sensor	Requires stable reference electrode; can be embedded in disposable cartridge
Moisture Content (Hydration)	40% – 65% hydration (relative)	Dry, flaky skin; impaired barrier function	Oily, swollen, or inflamed skin; possible barrier breakdown	Capacitive/impedance hydration sensor	Place on swab tip or reusable pad for capacitance reading; needs calibration
Sebum (Oiliness)	50 – 200 µg/cm²	Dry skin, reduced sebum protection	Oily skin, clogged pores, acne risk	Optical reflectance on lipid-sensitive film	Use transparent sebum film with LED reflectance sensor
Microbial Load	10^4 – 10^6 CFU/cm²	Disrupted flora; weakened immune defense	Overgrowth of bacteria/fungi; risk of infection or acne	ATP colorimetric pad or enzyme biosensor	Single-use colorimetric strip with reader or low-cost biosensor chip
Skin Temperature	32°C – 34°C	Poor circulation or metabolic activity	Inflammation, fever, infection, acne activity	Infrared thermopile sensor	Mounted near swab contact point; requires ambient compensation
Skin Color / Pigmentation	Melanin Index: 20–70, Redness Index: < 40	Hypopigmentation, anemia, dull appearance	Hyperpigmentation, inflammation, rosacea	RGB image sensor with calibration	Requires controlled lighting and color calibration for consistency
Pore Size / Visibility	Average pore diameter < 0.1 mm	Atypically small pores, possibly aged or dehydrated skin	Enlarged pores, excess sebum, acne-prone or photoaged skin	Macro lens + image processing algorithm	Requires high-resolution camera and edge detection algorithm

Summary Dashboard

Summary

Program Status:

Schedule	Resources	Risk	Cost

Project Cost Est.: **~8–10 FTEs for 24 months (Q3 2025 – Q2 2027).**

Prob. Technical Success: **~80% (based on proven sensor technologies + known predicates).**

Revenue Estimates **~$50M cumulative by Year 5 post-launch (U.S. + EU).**

PLC Phase: **Development & Verification.**

Software/Bioinformatics Needs: **AI-driven analytics, data security, multi-sensor data fusion algorithms.**

Resource Tracking

Functional Area	Nov 2015		Dec 2015		Jan 2016		Feb 2016		Mar 2016		Apr 2016	
	C	P	C	P	C	P	C	P	C	P	C	P
R&D (HW/Consumables)												
R&D (SW/AI Algorithms)												
Manufacturing												
Marketing												
Quality/Regulatory												
Project Management Organization (PMO)												

Key Project Milestones & Completion Date

(Modify table according to project needs)

Milestone	Original Target Date	Current Target Date	Date Completed
Phase 1 - Feasibility	**Q2 2025**	**Q2 2025**	Complete
Phase 2 - Definition	**Q3 2025**	**Q4 2025**	
Phase 3 - Development & Verification	**Q1 2026**	**Q2 2026**	
Phase 4 - Validation (Clinical Study)	**Q3 2026**	**Q1 2027**	
Phase 5 - Regulatory Submission (FDA 510(k), CE Mark)	**Q2 2027**	**Q3 2027**	

Significant Achievements

- Completed feasibility with working prototype.
- Positive feedback from dermatology KOLs on usability.
- Pre-Submission meeting with FDA scheduled (Q4 2025).
- Initial predicate comparison data generated.

Prioritized Risks / Issues

(Likelihood + Impact)

- Regulatory reclassification to higher risk class (Med/High).
- Variability of skin readings across demographics (Med).
- Potential delays in clinical validation recruitment (High).
- Cybersecurity compliance challenges (Med).

Deliverables for Next PLC Step / Next Phase

- Finalize clinical study protocol (Q4 2025).
- Complete bench testing and software validation plan.
- Submit FDA Q-Sub package.
- Identify EU Notified Body for MDR review.

Revenue Forecast & Assumptions

Metric	2025	2026	2027	2028	2029	2030
Clinics/Research Labs adopting	200	500	1,200	2,500	4,000	6,000
Hardware Units Sold	200	500	1,200	2,500	4,000	6,000
Disposable Probe Tips (units, K)	120K	360K	1.0M	3.0M	6.0M	10.0M
Software Subscriptions	150	400	1,000	2,200	3,600	5,500
ASP (Hardware, USD)	3,500	3,450	3,400	3,350	3,300	3,250
ASP (Disposables, USD)	2	2	2	2	2	2
ASP (Software, USD/yr)	500	500	500	500	500	500

Revenue Forecast & Assumptions

Year	Hardware Revenue	Disposables Revenue	Software Revenue	Total Revenue
2025	$0.70M	$0.24M	$0.08M	**$1.0M**
2026	$1.73M	$1.20M	$0.20M	**$3.1M**
2027	$4.08M	$3.20M	$1.30M	**$8.6M**
2028	$8.38M	$9.00M	$2.62M	**$20.0M**
2029	$13.20M	$16.00M	$4.80M	**$34.0M**
2030	$21.00M	$20.00M	$2.75M	**$43.8M**

Revenue Forecast & Assumptions Details

What is required to achieve the forecast? (e.g., # units per months sold, sales channel improvements, marketing campaigns, etc.)	• Secure regulatory clearance (FDA 510(k), CE Mark) by 2027. • Scale hardware production to meet forecasted 500 → 6,000 units/year. • Expand sales channels through dermatology clinics, cosmetic research, and wellness centers. • Drive adoption via KOL partnerships and evidence-backed marketing campaigns. • Build recurring revenue through consumables (probe tips) and SaaS subscriptions.
Justification for growth / ramp-up assumed on previous slide	• Rising demand for evidence-based skincare & digital dermatology tools. • Multi-sensor integration replaces multiple single-use devices → cost efficiency for clinics. • Recurring disposables model ensures sustained revenue growth. • Expansion into consumer wellness markets post-2028 fuels scale-up.
Cannibalization risk: description and estimate of financial impact	• Minimal risk: existing single-function analyzers (Corneometer, Sebumeter) may lose share, but DermaScan positions as multi-functional upgrade. • Impact estimate: <$2M loss in overlapping market segments, offset by >$40M incremental growth.
Risk of not pursuing: description and estimate of financial impact	• Loss of first-mover advantage in multi-analyte skin analysis market. • Competitors could capture early adoption in clinics and cosmetics → lost revenue opportunity of $30–40M by 2030. • Weakens cross-platform strategy with DermaDiet & DermaSkin ecosystem.
Explanation of any changes to forecast / launch date, etc. (since last iteration)	• Forecast extended by 6 months to allow for regulatory review time (FDA Q-Sub feedback). • Launch markets updated: U.S. + EU (2027), followed by Canada, Japan, Brazil (2028). • Adjusted revenue mix to reflect higher reliance on disposables after clinic adoption feedback.

Resource Requirement

	Category	Phase	# FTEs	Time	Types of FTEs	Notes	Cost
R&D & Related	R&D	1	4	6 mo	HW engineers, sensor specialists	Prototype + bench testing	$600K
		2	6	12 mo	SW devs, AI/data scientists, FW engineers	Full probe integration + app	$1.2M
		3	8	12 mo	HW, SW, QA, test engineers	Usability, EMC, biocompatibility	$1.6M
	BPI		2	6 mo	Process engineers	Supplier qualification & scaling	$300K
						Total:	**~$3.7M**

	Category	Region	Level	Notes		Date	Cost
Regulatory	Planned Clearances	US FDA	Class II	Q-Sub + submission		Q2 2027	$250K
		EU MDR	Class B	Notified Body + CE mark		Q3 2027	$300K
	Clinical trials	US & EU			Multi-center validation	Q3 2026 - Q1 2027	$1.5M
	RAQA	Global			ISO 13485, ISO 14971, ISO 62304 compliance	Continuous	$250K

	Category	Description / Explanation	Date	Cost
Marketing	Beta Testing, Early Access	• Partner dermatology clinics (10 sites)	2026	$150K
	Conferences	• AAD, EADV, MedTech Summit, CES	2026-2027	$200K
	Other	KOL engagement, digital marketing	Ongoing	$250K

	Category	Description / Explanation	Date	Cost
Other	Training	Clinician/operator training modules	2027	100K

Other Remarks

Free space to elaborate on topics not covered adequately in previous slides

AI & Data strategy	• DermaScan's AI algorithms are designed to provide trend analysis, normalization across demographics, and predictive skin health insights. • Data privacy & security will follow HIPAA, GDPR, and FDA Cybersecurity guidance. • Long-term opportunity to build a global skin health database, enabling clinical research, precision skincare, and cross-product integration with DermaDiet and DermaSkin.
Strategic Partnerships & Ecosystem	• Partnership opportunities with cosmetic brands, dermatology clinics, and wellness platforms for co-branded studies and validation. • Integration with supplement and skincare product personalization to strengthen recurring revenue. • Potential collaborations with academic dermatology research centers to expand clinical credibility. • Ecosystem positioning: DermaScan as the hardware + software foundation of the company's broader personalized health strategy.

DermaScan Product Regulatory Strategy

Regulatory and Product Intern: Hemal Kurani

Date: Aug 18, 2025

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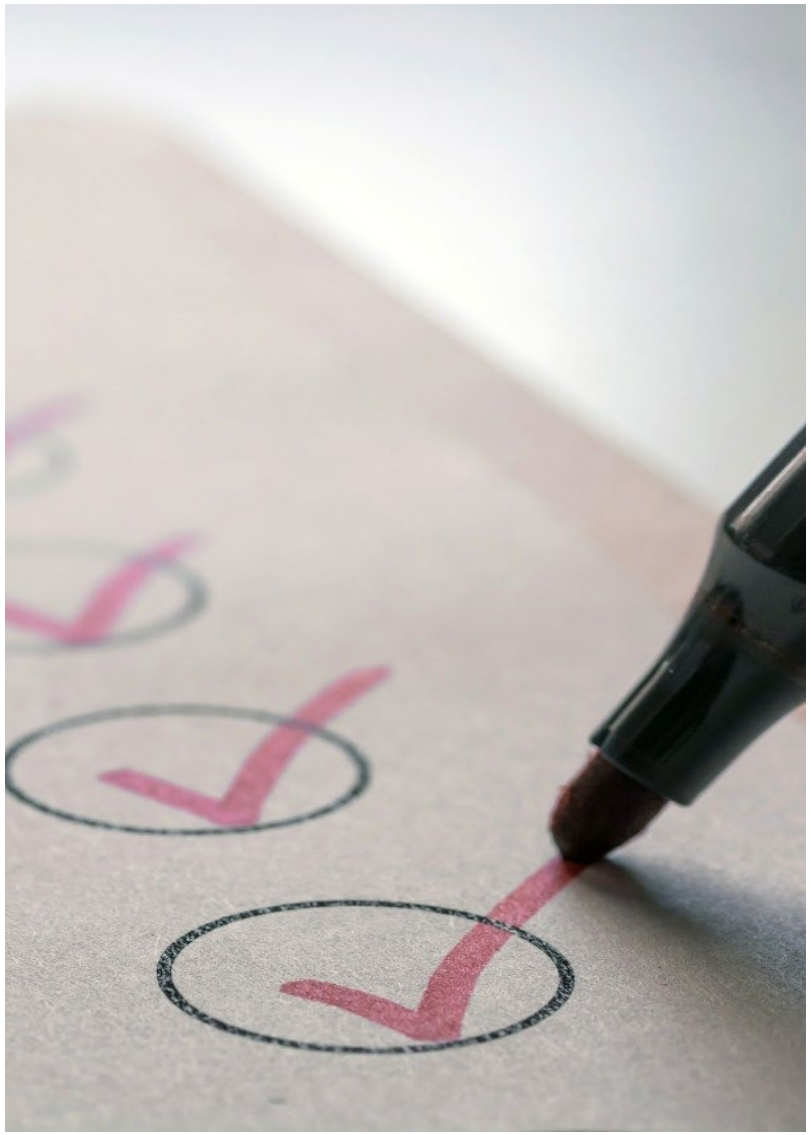


AGENDA

- Introduction
- Executive Summary
- Product Description
- Predicate Device Comparison
- Method Comparison / Clinical Trials
- Regulatory Risks and Mitigations
- Regulatory Approval Timeline
- FDA and EU Submission Contents
- Q & A

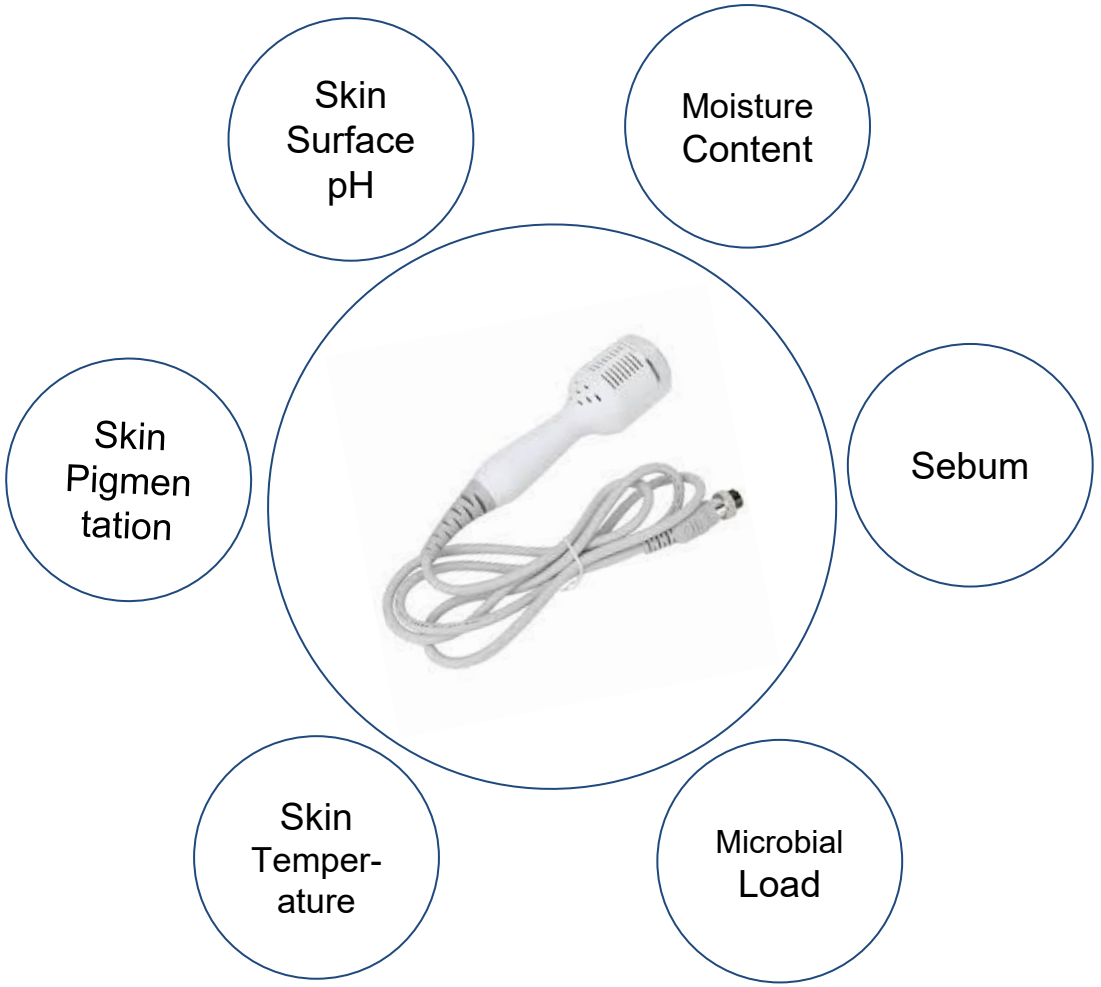
INTRODUCTION

- **Device Type**: Non-invasive dermatological sensor system
- **Intended Use**: Quantitative assessment of skin health parameters (hydration, pH, sebum, pigmentation, temperature, microbial load) to support dermatological and cosmetic evaluations
- **Regulatory Class (U.S.):** Class II (510(k) pathway anticipated)
- **Applicable FDA Regulations:**
    - 21 CFR 878.4800 (Skin Moisture Measurement Devices),
    - 21 CFR 878.4420 (Cutaneous Analysis Devices)
- **Pathway**: FDA 510(k) clearance; EU MDR Class IIa
- **Regulatory Strategy**:
    - Leverage predicate skin analyzers (hydration meters, sebum analyzers, spectrophotometry tools)
    - Claims limited to adjunctive measurement tool, not standalone diagnostic

INTENDED USE

DermaScan is a non-invasive skin analysis system intended to quantitatively measure skin parameters Skin Surface pH, Moisture Content (Hydration), Sebum (Oiliness), Microbial Load, Skin Temperature, Skin Color / Pigmentation

The device provides objective numerical data to support dermatological assessment, cosmetic research, and skincare product evaluation. It is intended to be used by clinicians, researchers, and trained professionals as an adjunctive tool to aid in the assessment of skin condition. DermaScan is not intended to provide a diagnosis or to serve as the sole basis for medical decision-making.



INTENDED USE DETAIL MEASUREMENTS

Parameter	Reference Range	Low Value Implications	High Value Implications
Skin Surface pH	pH 4.5–5.5	Barrier dysfunction, irritation, susceptibility to infection	Pathogen overgrowth, acne, inflammation
Moisture Content (Hydration)	40% – 65% hydration (relative)	Dry, flaky skin; impaired barrier function	Oily, swollen, or inflamed skin; possible barrier breakdown
Sebum (Oiliness)	50 – 200 µg/cm²	Dry skin, reduced sebum protection	Oily skin, clogged pores, acne risk
Microbial Load	10^4 – 10^6 CFU/cm²	Disrupted flora; weakened immune defense	Overgrowth of bacteria/fungi; risk of infection or acne
Skin Temperature	32°C – 34°C	Poor circulation or metabolic activity	Inflammation, fever, infection, acne activity
Skin Color / Pigmentation	Melanin Index: 20–70, Redness Index: < 40	Hypopigmentation, anemia, dull appearance	Hyperpigmentation, inflammation, rosacea
Pore Size / Visibility	Average pore diameter < 0.1 mm	Atypically small pores, possibly aged or dehydrated skin	Enlarged pores, excess sebum, acne-prone or photoaged skin

EXECUTIVE SUMMARY

- Target FDA 510(k) clearance and EU MDR conformity for DermaScan
- Combines multi-parametric skin sensor probe with AI-powered mobile app
- Strategy: Use predicate devices (Courage+Khazaka Corneometer, Skicon-200EX, Mexameter, Sebumeter, Skin Thermometer)
- Avoids De Novo or PMA by limiting claims to objective measurement of skin parameters
- Clinical validation with ~120 subjects for correlation vs. reference methods
- Target clearance/CE mark by Q4 2027 – Q1 2028

PRODUCT DESCRIPTION

System Overview:	Functionality:	Key Differentiators:
Handheld probe with embedded sensors (hydration, pH, sebum, temperature, optical spectroscopy, impedance) Companion mobile app with secure cloud data storage	Provides objective numerical readings of skin health parameters AI-enabled trending and reporting for clinicians, researchers, and consumers	Multi-analyte assessment in a single probe Real-time, user-friendly interface Potential for integration with personalized skincare and supplement recommendations

PREDICATE DEVICE COMPARISON

Feature	DermaScan	Predicate Devices	Regulatory Note
Parameters	Multi-sensor (hydration, pH, sebum, pigmentation, temp, microbial load)	Single-parameter tools (Corneometer, Sebumeter, Mexameter, pH probe, thermometer)	Multi-analyte = higher validation burden
Intended Use	Adjunctive skin condition measurement	Adjunctive single-parameter measurement	Claims must avoid diagnosis
Classification	FDA Class II (510(k)), EU MDR IIa	FDA Class II, EU Class I–IIa	Equivalent pathway if claims are limited
Form Factor	Handheld probe + mobile app (AI analysis)	Standalone probes	Software validation required (IEC 62304)
Safety & Biocomp.	IEC 60601, ISO 10993	Same	Comparable expectations
Usability	Multi-function → usability testing (ISO 62366)	Minimal usability needs	Higher HF burden for DermaScan
Clinical Data	~120 subjects; correlation vs reference	Smaller correlation studies	Larger, multiparametric validation likely

METHOD COMPARISON / BENCH TESTING

- **Bench Testing – Required**

Establishes core system performance and safety

- **Sensor calibration and repeatability**
- **Electrical safety & EMC (IEC 60601-1, -1-2)**
- **Biocompatibility (ISO 10993)**
- **Sterilization/cleaning validation (if reusable probe tips)**
- **Packaging validation**

METHOD COMPARISON / CLINICAL TRIALS

- **Non-Clinical Validation – In Parallel**

Demonstrates system integration, usability, and human factors compliance

- **Human factors usability (ISO 62366)**
- **Risk management (ISO 14971)**
- **Software validation (IEC 62304)**
- **Labeling validation**

METHOD COMPARISON / CLINICAL TRIALS

- **Clinical Study – Anticipated**

Supports real-world safety, efficacy, and user experience

- **Study size: ~120 participants**
- **Endpoints: correlation vs. reference methods (hydration, sebum, melanin, pH, temp)**
- **Outcome: demonstrate accuracy, reproducibility, usability**

➢Confirms clinical safety and performance

REGULATORY RISKS AND MITIGATION

Risk	Impact	Mitigation Strategy
FDA views device as diagnostic	510(k) pathway	Limit claims to adjunctive assessment
Insufficient predicate comparators	Delay / De Novo	Multiple device comparators + strong bench data
Clinical variability in skin readings	Reproducibility issues	Larger, diverse subject pool
Microbial Load Sensitivity is poor	Requires comparison with IVD test based on skin swab	Detect only few common microbes found in skin such as Cutibacterium acnes, Staphylococcus epidermidis, Corynebacterium spp., and Malassezia yeasts, with occasional colonization by S. aureus and Micrococcus
AI algorithm seen as “black box”	Extra review burden	Provide transparent validation and algorithm, Continuous Validation, Data Quality Checks and avoid bias based on skin color
MDR Class Iib reclassification	Higher cost & clinical requirements	Early Notified Body engagement

510(k) DeNovo Submission Contents

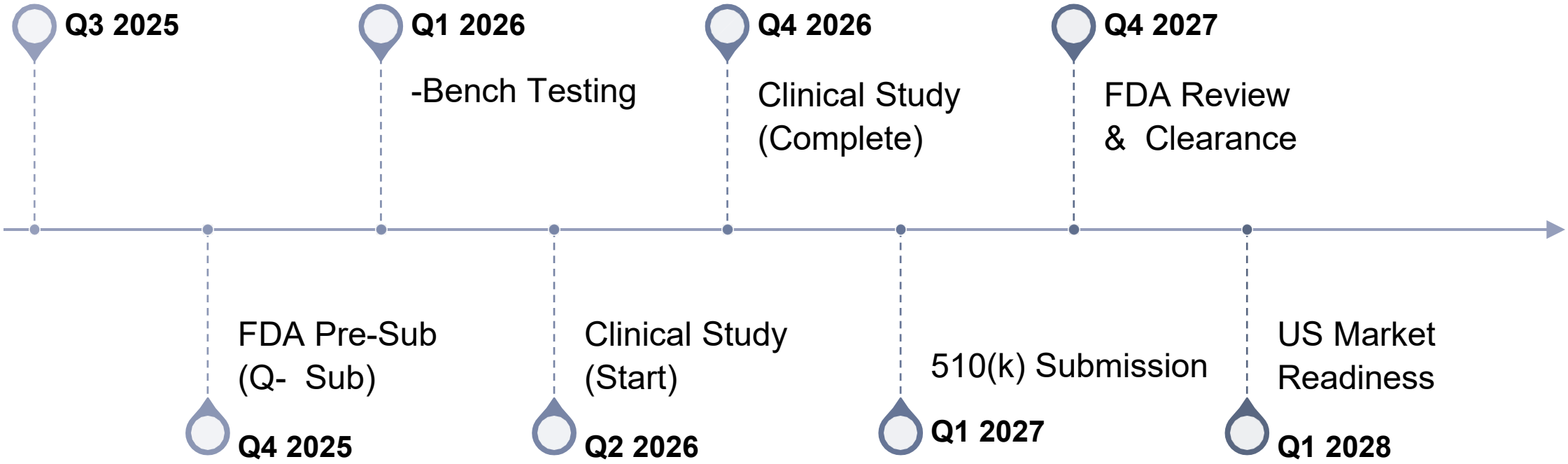
1	Medical Device User Fee Cover Sheet (Form FDA 3601) CDRH Premarket Review Submission	12	Substantial Equivalence Discussion
2	Cover Sheet	13	Proposed Labeling
3	510(k) Cover Letter	14	Sterilization and Shelf Life
4	Indications for Use Statement	15	Biocompatibility
5	510(k) Summary or 510(k) Statement	16	Software
6	Truthful and Accuracy Statement	17	Electromagnetic Compatibility and Electrical Safety
7	Class III Summary and Certification	18	Performance Testing – Bench
8	Financial Certification or Disclosure Statement	19	Performance Testing – Animal
9	Declarations of Conformity and Guidance Documents	20	Performance Testing – Clinical
10	Executive Summary	21	Other
11	Device Description		

EU Summary Technical Documentation Submission Contents

DermaScan Summary Technical Documentation

Appendix A – Labeling
Appendix B – Regulatory Classification
Appendix C – Design Information
Appendix D – Manufacturing
Appendix E – GSPR Checklist
Appendix F – Risk Management
Appendix G – Performance Evaluation
Appendix H – Stability Data
Appendix I – Software Documentation
Appendix J – Additional Data
Appendix K – Post Market Surveillance
Appendix L – Declaration of Conformity

REGULATORY APPROVAL TIMELINE



DIETARY & COSMETICS SOLUTIONS

Parameter	Problem	Diet Strategy	Dietary Supplements	Natural Cosmetic Face Mask	Artificial / Off-the-Shelf Face Mask
Skin pH	Too alkaline or too acidic	Antioxidants, omega-3s, reduce processed foods	Vitamin C, Vitamin E, Omega-3 (Fish Oil), Zinc, Astaxanthin	Apple cider vinegar + green tea (restores pH, antioxidant-rich)	Dr. Jart+ Cicapair Calming Mask, La Roche-Posay Cicaplast Mask (pH balancing and barrier repair)
Sebum (Oil)	Excess (oily skin, acne)	Low GI diet, reduce dairy, add zinc & vitamin A	Zinc, Vitamin A, DIM, Burdock root	Clay (bentonite/kaolin) + tea tree oil	Origins Clear Improvement Charcoal Mask, Neutrogena Clear Pore Cleanser/Mask, Innisfree Volcanic Clay
	Deficiency (dry, flaky skin)	Healthy fats, vitamin E, biotin	Omega-3, Biotin, Vitamin E, Evening Primrose Oil (GLA)	Avocado + honey + olive oil	LANEIGE Water Sleeping Mask, Clinique Moisture Surge Overnight Mask, CeraVe Hydrating Facial Mask
Moisture	Low hydration	Water, hydrating foods, omega-3s, potassium	Hyaluronic Acid, Ceramides, Electrolyte blends, Collagen peptides	Aloe vera gel + cucumber + glycerin	Hada Labo Hyaluronic Acid Sheet Mask, TONYMOLY I'm Real Aloe Mask, Dr. Jart+ Water Jet Vital Hydra
Microbial Load	Imbalanced microbiome	Prebiotics, probiotics, polyphenols, reduce sugar	Probiotics, Prebiotic fiber (Inulin/FOS), Lactoferrin, Green Tea Extract	Yogurt + honey + turmeric	Gallinée Prebiotic Face Mask, Aurelia London Probiotic Mask, Mother Dirt AO+ Mist (postbiotic spray)