



Press Kit

www.mediwhale.com

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I. About Us

Mediwhale is the AI-powered health diagnostics company that uses non-invasive retina scans to help prevent cardiometabolic diseases. Mediwhale’s solution uses deep learning algorithms to detect future disease risks even before symptoms appear. Mediwhale has been dedicated to making preventative care more affordable, accessible, safe, and convenient since being founded in 2016 in South Korea.



Photos of, from left to right, CPO Young Lee, CMO Tyler Rim, and CEO Kevin Choi.

- **Foundation**

Mediwhale’s founding began in 2016 when Kevin Choi, CEO of Mediwhale met Tyler Rim, CMO of Mediwhale at Severance Hospital, as a patient and doctor. This serendipitous meeting revealed Choi had lost 50% of his vision to glaucoma, sparking his ambition to create a technology capable of early disease detection before the onset of symptoms. Rim, driven by a passion to advance AI diagnostic technologies to enhance patient-focused care, shared this vision. Their concept for an AI diagnostic solution came to fruition with the joint of Young Lee, CPO of Mediwhale who won the "Medical Big Data Analysis Contest" at Seoul Asan Medical Center.

- **Mission**

Mediwhale is committed to enhancing AI technology to reduce the gap in healthcare access between medical professionals and the broader community. The company firmly believes in the potential of AI to revolutionize the healthcare sector by making preventative care more accessible and affordable.

- **Products**

Mediwhale’s product line includes AI diagnostic and predictive technologies that utilize the retina. The core technology analyzes retinal images to make assessment and prediction for future risk of cardiovascular, kidney, and eye diseases.

- i. **Dr. Noon CVD (cardiovascular disease)**: Retinal-based AI diagnostic software that predicts the future risk of cardiovascular disease.
- ii. **Dr. Noon CKD (chronic kidney disease)**: Retinal-based AI diagnostic software that predicts the

future risk of developing chronic kidney disease.

- iii. **Dr. Noon Fundus:** Retinal-based AI diagnostic software to diagnose eye diseases.

- **Clinical Evidence and Patents**

The functionality and clinical effectiveness of Mediwhale products have been extensively validated through papers published in the world's top medical journals, including The Lancet Digital Health, npj Digital Medicine, and other authoritative publications.

It has been officially approved and registered as a software as a medical device in 8 regions: South Korea, EU(CE), UK, Australia, Singapore, Malaysia, Indonesia, and Thailand, and holds over 50 registered and applied patents.

In South Korea, starting from June 2023, it is available for private payor reimbursement in Korea, making it the first outpatient medical AI software that is reimbursed in Korea.

II. Products

- **Dr. Noon CVD**

Dr. Noon CVD is a retinal-based AI diagnostic software that diagnosis and predicts the future risk of cardiovascular disease. The AI algorithm automatically analyze the blood vessels in the retina image and calculate the future CVD risk in real time. It shows the equivalent result to the coronary artery calcium score derived from cardiac CT scan, the most accurate method in predicting future CVD risk. It is a simple and safe test with no risk of radiation exposure, providing a quick and cost-effective approach that can be utilized especially in primary care where CT is not accessible.

Dr. Noon CVD is installed and actively used in over 90 hospitals across South Korea, UAE, and Italy, supporting clinicians in enhancing cardiometabolic risk assessment and early disease prevention. It's in the process of obtaining FDA approval.

- i. **Publication**

- Prediction of systemic biomarkers from retinal photographs: development and validation of deep-learning algorithms
- Deep-learning-based cardiovascular risk stratification using coronary artery calcium scores predicted from retinal photographs
- Validation of a deep-learning-based retinal biomarker (Reti-CVD) in the prediction of cardiovascular disease: data from UK Biobank
- Pivotal trial of a deep-learning-based retinal biomarker (Reti-CVD) in the prediction of cardiovascular disease: data from CMERC-HI
- Cardiovascular disease risk assessment using a deep-learning-based retinal biomarker: a comparison with existing risk scores

- ii. **Regulatory Approvals and Commercial Licensing**

- Selected for the New Excellent Technology (NET) in Korea; Dec. 2023
- Selected for the Postponement of New Health Technology Assessment (nHTA) in Korea; Apr. 2023.
- Selected for the Mayo Clinic Startup Program; Mar. 2023
- Won the CES 2023 Innovation Award; Nov. 2022
- Approved for Medical device from Food and Drug Administration of Thailand; Oct. 2022

- Approved for class III cardiovascular risk assessment medical device from the Ministry of Food and Drug Safety of Korea; Aug. 2022
 - Approved for Class IIa medical device from Indonesian National Agency for Drug and Food Control (NA-DFC); Apr. 2022
 - Approved for medical device from UK Medicines and Healthcare products Regulatory Agency and Class B medical device from Singapore Health Sciences Authority (HAS); Feb. 2022
 - Approved for Class IIa medical device from Australian Registry of Therapeutic Goods (ARTG); Dec. 2021
 - Approved for class B medical device from the Ministry of Health of Malaysia; Oct. 2021
 - Approved for CE as a class IIa medical device in EU; May 2021
 - Approved as an Innovative medical device by the Ministry of Food and Drug Safety of Korea; Dec. 2020
 - Certified for ISO 13485; Certified since 17 December 2020 - Valid until Dec. 2026
- **Dr. Noon CKD** *Under the Regulatory Approval Process in South Korea
- Dr. Noon CKD is a retina-based AI diagnostic software that predicts the future risk of developing chronic kidney disease. Dr. Noon CKD analyzes the blood vessels in the retina with a simple retinal scan without the need for blood or urine tests and shows the risk of developing chronic kidney disease.
- Compared to blood-based estimated glomerular filtration rate (eGFR) and proteinuria urinalysis, which are commonly used to measure the current status of chronic kidney disease development, Dr. Noon CKD shows more accurate results in its' identifying high-risk patients, especially in asymptomatic people without any kidney function abnormalities.
- The accuracy and effectiveness of Dr. Noon CKD has been featured at various medical conferences and journals, including the npj Digital Medicine and American Society of Nephrology(ASN)'s Kidney Week.
- i. **Publication**
 - Prediction of systemic biomarkers from retinal photographs: development and validation of deep-learning algorithms
 - Retinal Photograph-Based Deep Learning Predicts CKD Among People With Preserved Kidney Function
 - Non-invasive chronic kidney disease risk stratification tool derived from retina-based deep learning and clinical factors
 - Impact of retinal photography-based deep learning system on risk stratification for chronic kidney disease progression
 - ii. **Regulatory Approvals and Commercial Licensing**
 - Approved for clinical trial protocol from Ministry of Food and Drug Safety of Korea; Jan. 2024
 - Designated as a Breakthrough Device by the Ministry of Food and Drug Safety of Korea; Aug. 2023
 - Won the Chronic Kidney Disease Challenge organized by AstraZeneca; Jun. 2023

- **Dr. Noon Fundus**

Dr. Noon Fundus is a retinal-based AI diagnostic software that diagnoses referable eye diseases including retinal abnormality, glaucoma, and media opacity issues. Dr. Noon Fundus algorithms are based on a vast amount of high-quality medical data and have been rigorously validated by renowned medical experts, with an accuracy rate of over 96%, equivalent to that of an ophthalmologist.

A simple retinal photograph is taken to automatically measure retinal conditions that require referral, such as retinal abnormalities, glaucoma, and media opacities. Once these retinal problems are detected, Dr. Noon Fundus suggests that patients seek further evaluation by an ophthalmologist.

i. Clinical Evidence

- Multi-categorical deep learning neural network to classify retinal images: A pilot study employing small database
- Deep Learning Is Effective for Classifying Non-referable versus Referable Eye Condition using Fundus Photographs
- Efficacy of deep learning-based artificial intelligence models in screening and referring patients with diabetic retinopathy and glaucoma

ii. Regulatory Approvals and Commercial Licensing

- Approved for Medical device from Food and Drug Administration of Thailand; Oct. 2022
- Approved for Class IIa medical device from Indonesian National Agency for Drug and Food Control (NA-DFC); Apr. 2022
- Approved for medical device from UK Medicines and Healthcare products Regulatory Agency and Class B medical device from Singapore Health Sciences Authority (HAS); Feb. 2022
- Approved for Class IIa medical device from Australian Registry of Therapeutic Goods (ARTG); Dec. 2021
- Approved for class B medical device from the Ministry of Health of Malaysia; Oct. 2021
- Approved for CE as a class IIa medical device in EU; May 2021
- Approved as a medical device by the Ministry of Food and Drug Safety of Korea; Aug. 2020

III. Mediwhale in Media

- The eyes have it: How Mediwhale is revolutionizing preventive health care
- [JPM2025] ‘Global pharma showed interest in Mediwhale after we verified AI diagnostic solution Dr. Noon’
- Mediwhale pushes for FDA approval to bring AI retinal scan to US cardiovascular prevention
- Mediwhale Secures \$12 Million in Series A2 Funding to Drive Global Leadership in Cardiovascular and Metabolic Disease Management
- A 26-year-old founded a medical startup — the same year he lost almost half his vision
- [Interview] Mediwhale CEO Kevin T. Choi, CMO Dr. Tyler H. Rim, and CPO Young G. Lee

IV. Media Contact

For any questions or clarifications, feel free to reach out using the contact details provided below.

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