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Revenio's iCare DRSplus included in FDA-cleared AI solution for diabetic retinopathy screening

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Revenio's iCare DRSplus fundus imaging system is included in an FDA-cleared AI-based solution in the United States in which images captured with the iCare DRSplus fundus imaging system are used for automatic screening of diabetic retinopathy.

The U.S.-based health technology company iHealthScreen has received FDA 510(k) clearance for its iPredict-DR™ AI software, which analyzes images captured with the iCare DRSplus fundus imaging system and automatically identifies patients who require screening for diabetic retinopathy. The solution is designed particularly for use in primary care where AI can help improve access to screening and accelerate patients' referrals for further examinations.

Diabetic retinopathy is one of the most common causes of preventable vision impairment worldwide. Early detection plays a key role in preserving vision, but participation in screening remains insufficient in many places, including the USA. By supporting efficient and scalable screening pathways, AI can help identify patients who need further assessment.

This is the first time that iCare DRSplus has been included in an FDA-cleared AI-based screening solution in the United States. The milestone supports Revenio's strategy to strengthen its position as a leading player in the diagnostics of eye diseases and to promote the adoption of digital and AI-enabled solutions as part of comprehensive eye health diagnostics.

"This is an important technological achievement both for the iCare DRSplus fundus imaging system, iHealthScreen and for our strategy. AI will transform the screening and diagnostics of eye diseases, and partnerships such as the one with iHealthScreen enable us to harness innovations to meet our customers' needs. It is great to see iCare DRSplus being used as part of the first FDA-cleared AI solution in the United States. This strengthens the market position of our products and supports our goal of improving the early detection of eye diseases worldwide," says Revenio's CEO **Jouni Toijala**.

"FDA clearance of iPredict-DR marks an important step toward making diabetic retinopathy screening more accessible in primary care and diabetes-care settings. By combining iPredict-DR's autonomous AI with the iCare DRSplus imaging system, healthcare providers can identify patients who may require referral for eye-care evaluation during a routine visit. We are excited to work with iCare to expand access to early diabetic retinopathy detection and help reduce preventable vision loss", said **Alauddin Bhuiyan**, PhD, President and CEO of iHealthScreen Inc.

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Revenio Group in brief
Revenio is a leading turnkey solutions provider in the global eye care market. The group offers fast, user-friendly, and reliable tools for diagnosing a wide variety of eye diseases. Revenio's solutions include e.g. tonometers, fundus imaging devices, optical coherence tomography (OCT), perimeters, multimodal devices, refraction systems, and software solutions under iCare and Visionix.

In May 2026, Revenio joined forces with Visionix, creating the most innovative, creative and comprehensive entity serving eye care professionals across optometry, optical retail and ophthalmology. In 2025, the Group's net sales totaled EUR 109.7 million, with an operating profit of EUR 25.4 million. Revenio Group Corporation is listed on Nasdaq Helsinki with the trading code REG1V.

Attachments

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