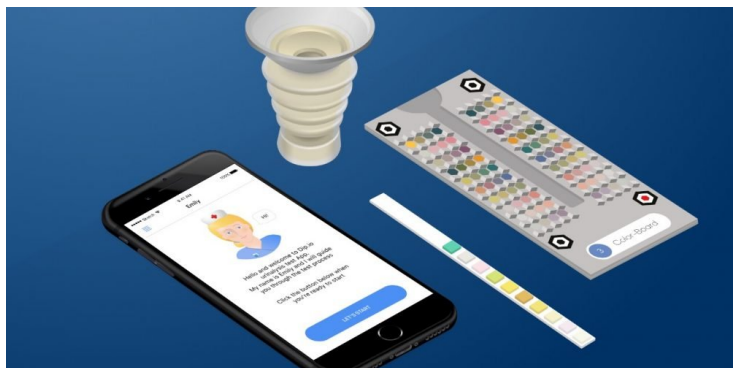


Now your smartphone camera can perform clinical urinalysis at home

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U.S. FDA Grants Landmark Class II Approval for Clinical Grade Smartphone Testing - Healthy.io's Dip.io Urinalysis



Israel based Healthy.io, the first company in the world to enable the smartphone camera to be used as a clinical grade diagnostic device, announced that it received Class II U.S. Food and Drug Administration (FDA) approval for the first product of its expanding digital health product portfolio: Dip.io.

Dip.io is a home-based, smartphone-enabled urinalysis kit that lets patients conduct clinical grade urine tests in the privacy of their own home. It is the first time the FDA has ever granted Class II approval for smartphone urine testing.

Approval Helps Healthy.io Usher in Era of Medical Selfie, Leveraging Embedded Smartphone Cameras to Improve Patient Adherence and Outcomes and Curb Healthcare Expenditures

Millions get their urine tested every day ; pregnant women, those suffering from kidney disease, diabetes, high blood pressure and others, but doing it in the lab is time consuming and cumbersome.

Conducting the same test in the comfort of one's home using a smartphone can improve patient outcomes enormously while potentially saving billions of dollars in healthcare expenditures through better access and prevention.

While other mobile health technology companies have been granted FDA approval, this is the first time the agency cleared a device based solely on existing smartphone cameras for Class II clinical claims. This ruling is an indication of the company's impact on the digital health industry and expanding clinical value.

The landmark FDA approval marks the culmination of a strong growth period for Healthy.io. In April, a study initiated by the National Kidney Foundation (NKF) and Geisinger, based on the Healthy.io adherence-as-a-service platform, demonstrated significant adherence improvement compared to standard of care. Full details of the study will be published later this year.

Healthy.io's home urine testing is set to be utilized by 100,000 users by the end of 2018 across patient pathways, with partners looking to shift more and more urine tests from the lab to the home.

In the UK, Healthy.io has been selected for the NHS Innovation Accelerator as a key technology and has been made available nationally through the G-Cloud procurement framework.