FDA Approves Ingestible Sensor That Tracks Health From The Inside

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The US Food and Drug Administration has approved an ingestible digital sensor that can be swallowed in a pill to track health data from inside the body. The idea is that the data can be used not only by patients themselves, but also by caregivers and doctors to individualize their care.

The ingestible sensor, formerly known as the Ingestion Event Marker or IEM, is already approved for use in Europe.

It is the first "digital pill" to receive FDA approval, in a move that its maker Proteus Digital Health, whose headquarters are in Redwood City, California, sees as the start of a era where digital medicine "shifts the care paradigm".

On Monday, George Savage, co-founder and chief medical officer at Proteus Digital Health, told the press:

"We are thrilled to have achieved this important milestone to market our ingestible sensor in the United States now, as well as in Europe."

"We are very much looking forward to bringing the benefits of our ingestible sensor to the American public in the form of innovative product offerings," he added.

The ingestible sensor, which is about the size of a grain of sand and made mostly of silicon, is part of an integrated system designed to give patients and their doctors "end-to-end personal health management".

Embedded in a pill or tablet, the device can help keep an eye on whether patients are taking their medications at the prescribed time and rate.

This is important, because although the effectiveness and safety of drugs are established in clinical trials, those tend to follow well-controlled conditions, with patients taking their drugs at the prescribed rates in the right quantities.

But at home, adherence to prescribed regimens may not be so easy to monitor, and without information about precisely when patients are taking their medication, doctors can't see if that is the problem, should the drug not work as it should.
The sensor does not contain a battery, it works like a "potato battery" that children make in science lessons at school. It has two conductive materials, one on either side. When these get wet in the stomach, they power the sensor for a short amount of time.

So once it comes into contact with stomach fluid, the sensor powers up, and "communicates a unique signal that determines identity and timing of ingestion", says Proteus.

The ingestible sensor passes through the body in much the same way as high-fiber food, according to information on the company's website.

The signal that it sends from the stomach travels through the patient's body to a patch worn on the skin. The patch contains technology that senses the signal and records the exact time the ingestible sensor was swallowed.

The patch can then send this information to a mobile phone application, and with the consent of the patient, be passed on to doctors and caregivers, so they can provide better quality care.

Proteus says its integrated "feedback" system is also designed to collect a range of other measurements, such as for heart rate, body position and activity.

Eric Topol, geneticist and cardiologist, is a professor of genomics at The Scripps Research Institute and wrote a book called "The Creative Destruction of Medicine: How the Digital Revolution Will Create Better Healthcare" where, among other things, he says technology that gives doctors a continuously updated picture of what is happening with each patient, will help them provide better, individualized care.

Topol told the press:

"The FDA validation represents a major milestone in digital medicine. Directly digitizing pills, for the first time, in conjunction with our wireless infrastructure, may prove to be the new standard for influencing medication adherence and significantly aid chronic disease management."

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References:
Source: Proteus Digital Health.