

## FDA Approves Digestible Microchips to Be Placed in Pills

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August 3, 2012 — The US Food and Drug Administration (FDA) has approved the first ingestible sensor. The *Ingestion Event Marker* (IEM), by Proteus Health, represents a new category of medical device: It is made entirely of ingredients found in food and is activated on ingestion.

"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," Eric Topol, MD, professor of genomics at the Scripps Research Institute in La Jolla, California, said in a company news release. Dr. Topol is the author of *The Creative Destruction of Medicine: How the Digital Revolution Will Create Better Healthcare*.



**The Proteus digital health feedback system combines an ingestible sensor placed on a pill, with a wearable sensor on an adhesive patch, and a mobile application that displays data on a mobile device, such as a smartphone.**

The sensor resembles a grain of sand in size, is made primarily of silicon, and can be integrated into an inert pill or any other ingestible object (such as a pharmaceutical). The Proteus *Digital Health* feedback system integrates wearable and ingestible sensor technologies to detect medication intake and physiologic data.

A disposable patch is worn on the body to capture and relay the body's physiological response and behaviors. In addition to recording information from the sensor, the patch records heart rate, temperature, activity, and rest patterns. The patch lasts approximately 7 days and is operated by a battery, which also lasts approximately 7 days.

A mobile device is then carried in the pocket or purse to display data in context and support care.

The sensor can be used to detect the exact time medication is taken, as well as the unique identity of the medication. The information is controlled by the patient.

The IEM does not contain a battery. Instead, the fluids in the stomach power the sensor, and the body transmits the digital signal generated by the sensor. The IEM is the only ingestible sensor that is powered by the body. The sensor passes through the body similar to fiber.

The system, which used to be known as the Raisin System, received European regulatory approval in August 2010. The technology has been used for thousands of days by patients in clinical trials without serious adverse events. The system does not appear to interfere with other medical devices.

Proteus Digital Health does not quantify the price, but rather states on their Web site that, "The cost will depend on the context in which the system is being used."

*Dr. Topol has disclosed no relevant financial relationships.*

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