

solianis monitoring ag

Solianis Holding AG (Solianis) is a **Swiss Medical device company** developing a **non-invasive, continuous glucose monitoring device** for diabetic patients. Solianis is owned and managed by experienced Medtech experts.

Market

Diabetes is one of the world's biggest global health threats. The World Health Organization (WHO) recently estimated that there are over 170 million people affected by diabetes worldwide. Today, the **established method to monitor the blood glucose profile** is to draw a small amount of blood from the fingertips and determine the glucose level via a portable glucose-monitoring instrument. This is typically done 2 to 5 times a day, in some cases even more than 10 times, a process that is painful and impacts regular monitoring. This method also measures blood glucose level at a single point in time. There is a growing medical interest not only among patients as well as among health care professionals to be able to monitor more continuously trends and patterns in glucose levels to provide greater reduction in the risk of long-term diabetic complications and serious hypoglycemic incidents.

Competition

There are **minimally-invasive monitoring devices** already on the market, but the drawbacks of these devices are the irritation of skin and/or tissue by the sampling method as well as the limited time of use (typically 3 to 5 days lifetime per sensor). Several companies are working to develop a **truly non-invasive** glucose monitoring device, but no device to date has proven itself reliable enough to be used in everyday life.

Technology

The technology pursued by Solianis was earlier developed by Pendragon Medical and is based on impedance spectroscopy. This technology allows **tracking of glucose variations under controlled conditions**. Finger stick testing is needed to calibrate the device as well as to perform baseline adjustments. Therefore, it is not a replacement of the traditional method, but provides additional benefits to the patient by monitoring the changes in glucose levels continuously, especially during the night. Although the device has shown acceptable data under controlled conditions, there were deviations in **field experiments**, which were attributed to additional effects.

Solianis acquired the IP portfolio from Pendragon, upon its liquidation, and developed a **R&D roadmap** that leads through a clearly defined pathway to several improvements on the soft- and hardware to increase the device' applicability and reliability. In order to address the impact of additional effects, a **multi-sensor platform** has been designed around the impedance spectroscopy based concept, including optical sensor technology to improve the reliability of the output. A recent clinical trial in cooperation with the University Hospital of Zurich, Switzerland, showed that the new sensor array reliably tracks glucose changes in healthy subjects as well as diabetic patients.

Milestones

By March 2007, first results of a **clinical study under simulated daily life conditions** will be available. By the end of 2007, the device will be tested in a **home-use setting to demonstrate the reliability**. A final prototype of the device will be ready by summer 2008 for the next clinical studies to gain data for **CE approval for Europe**. Clinical trials in the US for the purposes of getting a FDA approval will be initiated thereafter with expected FDA approval by end of 2012.

Contact

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