

Updated Information on Artificial Pancreas Systems

U.S. Food & Drug Administration

The FDA is helping advance the development of an artificial pancreas system -- an innovative device that automatically monitors blood glucose and provides appropriate insulin doses in people with type 1 diabetes.

FDA's efforts include prioritizing the review of research protocol studies, providing clear guidelines to industry, provide the most flexible recommendations to guide Sponsors in designing and testing these devices that are consistent with the least burdensome principle to provide options while assuring that testing is adequate to support marketing approval, setting performance and safety standards, fostering discussions between government and private researchers, sponsoring public forums, and finding ways to shorten and streamline study and review time.

In June 2011, the FDA released [Draft Guidance for Industry and the Food and Drug Administration Staff: The Content of Investigational Device Exemption \(IDE\) and Premarket Approval \(PMA\) Applications for Low Glucose Suspend \(LGS\) Device Systems](#) [1] to help provide clarity for manufacturers, investigators and reviewers in the development of the artificial pancreas system. It proposes safety and effectiveness goals that the FDA may require researchers and industry to meet when developing a type of artificial pancreas system called a Low Glucose Suspend System.

In December 2011, the FDA released a second [draft guidance for Industry and FDA Staff: Content of Investigational Device Exemption \(IDE\) and Premarket Approval \(PMA\) Applications for Artificial Pancreas Device Systems](#) [2], which aims to provide adequate guidance and instruction to facilitate the development and marketing of an artificial pancreas system while, at the same time, adopting a flexible approach.

There have been tremendous strides made in the research and development of an artificial pancreas system, and there are many research projects underway looking at their feasibility. For more information on these and other clinical trials, visit www.clinicaltrials.gov [3].

On this website you can learn more about what an artificial pancreas system is, research challenges associated with its development, and find out more about FDA's ongoing commitment to helping manufacturers develop safe and effective artificial pancreas system.

NOTE: The artificial pancreas systems described on this site do not involve biomaterial, synthetic or artificial tissue or organs.

[SOURCE](#) [4]

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Links:

[1] <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm259301.htm>

[2] <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm281706.htm>

[3] <http://www.clinicaltrials.gov>

[4] <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/ArtificialPancreas/default.htm>