BioSpectrum
the business of Bio & Health Sciences

FDA warns against use of unapproved devices for diabetes

20 May 2019 | News

The FDA is aware of manufacturers illegally marketing unauthorized devices for diabetes management

The U.S. Food and Drug Administration is warning patients and health care professionals of risks associated with the use of unapproved or unauthorized devices for diabetes management, including continuous glucose monitoring systems, insulin pumps and automated insulin dosing systems.

In the safety communication issued recently, the agency noted that the use of unapproved or unauthorized devices could result in inaccurate blood glucose (sugar) measurements or unsafe insulin dosing, which can lead to injury requiring medical intervention or even death.

The FDA is aware of manufacturers illegally marketing unauthorized devices for diabetes management, which have not been reviewed by the agency for safety and effectiveness. Companies are also illegally marketing components, such as unauthorized continuous glucose monitors that some patients may integrate into unauthorized automated insulin dosing systems. Additionally, the FDA is aware of patients combining devices or components that are not intended for use with other devices.

The FDA recommends that patients talk with their doctor about appropriate diabetes management devices for their needs and to only use devices and components that have been reviewed by the agency for safety and effectiveness.