Generic Name:
Insulin delivery and monitoring device
Trade Name:
MiniMed 670G hybrid closed looped system
Company:
Medtronic
Notes:

FDA has expanded the approval of the MiniMed 670G hybrid closed looped system, a diabetes management device that is intended to automatically monitor glucose and provide appropriate basal insulin doses with little or no input from the user, to include individuals aged 7 to 13 with type 1 diabetes.

FDA originally approved this device in September 2017 for use in patients aged 14 years and older with type 1 diabetes. The device works by measuring glucose levels every 5 minutes and automatically adjusting insulin delivery by either administering or withholding insulin.

The system includes a sensor that attaches to the body to measure glucose levels under the skin, an insulin pump strapped to the body, and an infusion patch connected to the pump with a catheter that delivers insulin. While the device automatically adjusts insulin levels, users need to manually request insulin doses to counter carbohydrate consumption at mealtime.

Approval was based on data from a clinical trial that included 105 individuals aged 7 to 11 years. Study participants wore the device for approximately 3.5 months and participated in three phases of the study to evaluate both at-home use as well as remote use. That study found no serious adverse events associated with use of the MiniMed 670G and that the device is safe for use in people aged 7 to 13 years with type 1 diabetes.

Risks associated with use of the system may include hypoglycemia, hyperglycemia, as well as skin irritation or redness around the device?s infusion patch.

As part of this approval, FDA is requiring a postmarketing study to evaluate device performance in real-world settings in children between the ages of 7 and 13. This device is not approved for use in children aged 6 years or younger or in individuals who require less than eight units of insulin per day.

Medication Monitor Categories:
Supplemental Approvals