MiniMed Newsroom

Medtronic Diabetes resolves warning letter, clearing path for future innovations

Resolution follows the recent FDA approval of the MiniMed™ 780G system featuring the world's first and only automated insulin delivery system with real-time meal detection technology*

DUBLIN, April 25, 2023 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced that the U.S. Food and Drug Administration (FDA) lifted the warning letter received at the company's Diabetes headquarters in Northridge, California, in December 2021. This follows on the heels of last week's FDA approval of the MiniMed™ 780G system, the world's first and only automated insulin delivery system with meal detection technology* that provides automatic adjustments and corrections† to glucose levels every 5 minutes.§

The resolution of the warning letter follows ongoing remediation actions from the company and proactive actions to continue to strengthen its quality systems. All regulatory restrictions associated with the warning letter have been resolved.

"We're very thankful to the agency for working with us so collaboratively to ensure we're able to work as quickly as possible to address the needs of the diabetes community," said Que Dallara, EVP and President of Medtronic Diabetes. "Clearing this latest regulatory milestone allows us to focus on what's most important – delivering innovations that address unmet needs for the individuals with diabetes we have the privilege to serve. It's an honor that we never take for granted and our commitment is to ensure we're putting patients first and prioritizing safety and quality above all."

www.medtronicdiabetes.com

Medtronic Diabetes is on a mission to alleviate the burden of diabetes by empowering individuals to live life on their terms, with the most advanced diabetes technology and always-on support when and how they need it. We've pioneered first-of-its-kind innovations for over 40 years and are committed to designing the future of diabetes management through next-generation sensors (CGM), intelligent dosing systems, and the power of data science and AI while always putting the customer experience at the forefront.

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 90,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

*Taking a bolus 15 – 20 minutes before a meal helps to keep blood sugar levels under control after eating.
† Refers to auto correct, which provides bolus assistance. Can deliver all auto correction doses automatically without user interaction, feature can be turned on and off.
§ Refers to SmartGuard™ feature. Individual results may vary.

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