CLOSER LOOK

MEMORANDUM

FDA clears seven-day dosing for CeQur Simplicity plus new 1U dosing device from CeQur – June 4, 2026

Switzerland-based CeQur announced today two FDA clearances: extended seven-day wear for its CeQur Simplicity insulin patch and a new one-unit dosing device. CeQur Simplicity is a wearable insulin patch that holds up to 200 units of rapid-acting insulin and is approved for people with diabetes ages 21 and older taking mealtime insulin. The patch was launched in 2021 and wear time was expanded to up to four days in June 2024. CeQur said that today's further wear time extension will minimize patient burden for mealtime dosing by reducing device changes– of note, the seven-day wear time offers an advantage over Insulet's Omnipod 5 patch pump. The new one-unit device, compared to the current two-unit dosage, will improve individualized options for insulin dosing. CeQur aims for this to be particularly beneficial to patients seeking tighter management or those with lower mealtime insulin needs.

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CeQur Simplicity is designed to offer alternatives for patients on MDI

The CeQur Simplicity insulin patch is designed to replace bolus insulin injections for people on MDI of insulin. The device measures 65 x 36 mm, approximately the same area as Omnipod 5 but less than half as thick. The device is labeled for use with U100 Humalog and Novolog and can also be worn for up to 30 minutes in water.

CeQur's previous analyses have found that nearly two-thirds of patients studied do not feel comfortable injecting insulin in front of others, leading to the company's focus on discretion with its small form factor.

CeQur to present posters featuring real-world data at the upcoming ADA 86th Scientific Sessions

Together with today's exciting regulatory announcements, CeQur provided detail on its upcoming clinical research posters to be presented at ADA 2026 beginning Friday. Real-world data from 1,073 adults will be presented that discusses care simplification and lower patient burden:

- **Poster #1865-P:** Advancing Diabetes Care by Simplifying Insulin Delivery by A. Carlson, J. Duffee, L. Morini, J. Allaire, C.G. Parkin, and C. Carter; and
- **Poster #1867-P:** Lowering Diabetes Treatment Burden Through a Simple Switch to Insulin Patch Therapy by A. Carlson, J. Duffee, L. Morini, J. Allaire, C.G. Parkin, and C. Carter.

CeQur will also staff booth #1205 in the exhibit hall – be sure to visit the many insulin delivery exhibitors in attendance at ADA 2026!

Close Concerns' Questions

1. Will the one-unit device feature the CeQur Simplicity branding, or will it be promoted as another device? The 1U device will maintain the CeQur Simplicity brand.
2. Is the longer wear time clearance based on any changes to the device or further FDA evaluation? Further FDA evaluation.
3. Does CeQur see CeQur Simplicity as a potential transition device for patients going from MDI to insulin pump therapy, more of a long-term solution, or both? Most people use CeQur Simplicity as a long-term solution instead

of MDI.

-- by Nour Khachemoune, Monica Oxenreiter, and Kelly Close