CLOSER LOOK

MEMORANDUM

Tandem's Control-IQ+ becomes the first approved FDA-cleared AID system available for T1D pregnancy in the US – April 27, 2026

CIRCUIT trial results show +3 hours/day in pregnancy range; Control-IQ+ becomes third AID system cleared for pregnancy around the globe

Tandem announced today that the FDA has cleared its Control-IQ+ algorithm for use during pregnancy for people with T1D, expanding the label for both the t:slim X2 and Mobi pumps. This marks a major regulatory milestone for diabetes technology in maternal care as Control-IQ+ becomes the first commercially available AID system in the US specifically indicated for pregnancy in T1D. The label follows the company's 510(k) submission announced on the 4Q25 call in mid-February of this year. This decision was supported by results from the CIRCUIT trial (n=88) from October 2025. Tandem plans to launch provider education for this indication beginning at ADA 2026 – we look forward to learning more as well as seeing the exhibition booth – this is a big win for Tandem, as pregnancy trials are difficult to design and fund and being "first" in the US strikes us as a real victory for the company.

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CIRCUIT trial provides evidence base by showing strong glycemic benefit throughout pregnancy

FDA clearance was supported by the CIRCUIT trial, a 14-site randomized controlled trial across Canada and Australia comparing the t:slim X2 pump with Control-IQ to standard care in pregnant women with T1D (n=88). From 16 weeks of gestation through delivery, participants using Control-IQ achieved a mean Time in Pregnancy Range (TIPR; 63-140 mg/dL[1]) of 65% versus 50% with standard care, a ~12.6% improvement equivalent to roughly three more hours per day in the pregnancy target range. Other findings include:

- **Durable glycemic benefit:** Glycemic improvements emerged within the first week after Control-IQ initiation with median TIPR rising from about 55% to nearly 70% and remaining durable through gestation with particularly strong overnight gains. By late pregnancy, TIPR approached 75%, which the authors indicated as a notable outcome especially given increased insulin resistance in the third trimester.
- **Maternal outcomes:** Beyond TIPR, Control-IQ users achieved lower A1c values (-0.5% at 24 weeks and -0.4% at 34 weeks from a baseline of 7.3%), lower total daily insulin requirements (about 28 units/day less), and numerically lower preeclampsia rates (14% versus 25%).
- **Comparable safety outcomes:** Safety outcomes were comparable, with one severe hypoglycemic event and two diabetic ketoacidosis (DKA) events in the Control-IQ group versus one instance of DKA and one postpartum severe hypoglycemia event in standard care. Neonatal outcomes were generally similar, though hyperbilirubinemia and NICU stays over 24 hours were modestly higher in the closed-loop group.

Taken together, CIRCUIT offers clear support for the pregnancy-specific efficacy and safety of Tandem's Control-IQ AID system.

Pregnancy AID landscape is expanding globally but regional access and system design still differ

Tandem's US clearance adds an important new option for pregnant women and joins an international shift toward

pregnancy-specific AID systems. In Europe, CamDiab's CamAPS FX (CE-Mark received in March 2020) and Medtronic's MiniMed 780G (CE-Mark received in July 2025) are already approved for pregnancy use in T1D and T2D. While CamDiab's CamAPS FX algorithm received FDA clearance for people with T1D in May 2024, including during pregnancy, the algorithm does not yet have a compatible insulin pump partner that is cleared in the US. This means that Tandem's clearance will make its systems the first commercially available to US women. This approval is notable as it may accelerate payer, provider, and regulatory momentum in a population with historically unique glycemic challenges.

System	Regulatory Status	Key Evidence	CGM Integrations
Tandem Control-IQ+ (t:slim X2/Mobi)	FDA cleared (April 2026)	CIRCUIT (n=88)	Dexcom G6 and G7, FreeStyle Libre 3 Plus
MiniMed 780G	CE Mark (July 2025)	CRISTAL (n=95)	Guardian 3 and 4, Simplera Sync, Instinct
CamAPS FX	CE Mark (March 2020)	AiDAPT (n=124)	FreeStyle Libre 3 and Libre 3 Plus, Dexcom G7

Regulatory clearance may have broader implications

Formal pregnancy clearance reflects growing recognition that pregnancy presents one of the most demanding glycemic management settings in diabetes care, as it requires (i) tighter targets represented by TIPR; (ii) rapid adaptation to changing insulin resistance; and (iii) elevated safety considerations. Historically, these challenges have left the use of many AID systems off-label despite increasing real-world use. Tandem's planned provider training starting at ADA 2026 suggests the company recognizes that clinical implementation will determine impact.

Close Concerns' Questions

1. Will FDA clearance meaningfully improve payer coverage and clinician confidence for AID initiation in pregnancy? If so, what stage of pregnancy are recommendations likely?
2. How will Control-IQ+ compare with CamAPS FX and MiniMed 780G in real-world pregnancy outcomes?
3. Will Tandem pursue pregnancy-specific algorithm refinements?
4. Will Tandem also pursue CE Mark for this population?

-- by Riya Chatterjee, Nour Khachemoune, Jeremy Alkire, and Kelly Close

[1] Time in Pregnancy Range (TIPR) is defined by the ADA 2026 Standards of Care is 63-140 mg/dL with a recommended goal of over 70% for pregnant women with T1D.