

K253534 Pivot Insulin Delivery SystemApr 8, 2026
146 days to decisionK253534 · Product code: **LZG** · Chemistry
Source: <https://www.510kdatabase.net/k253534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Insulin (LZG)
Date received	Nov 13, 2025
Decision date	Apr 8, 2026
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Modular Medical
Location	San Diego, CA, US
Contact	Shahzaib Rai
Website	https://www.modular-medical.com
510(k) history	1 submissions · 1 cleared · 2026-2026

Modular Medical develops simplified diabetes management technology designed for patients transitioning from manual insulin injections. The company is based in San Diego, California, and focuses on making insulin pump therapy accessible to those who find traditional devices overwhelming. The company has received FDA 510(k) clearance from total submission. Modular Medical specializes in Chemistry devices for diabetes care. The company achieved its first clearance in 2026 and remains active in regulatory submissions. The Pivot Insulin Delivery System represents the company's...