

K250983 Medblue Skin Prick Test Applicator (AS103, AS108, AS109, AS110, AS111, AS113, AS132, AS134, AS146, AS148, AS160, AS162, AS170, AS172)Jan 30, 2026
305 days to decisionK250983 · Product code: **SCL** · General Hospital
Source: <https://www.510kdatabase.net/k250983/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Allergen And Vaccine Delivery Needles (SCL)
Date received	Mar 31, 2025
Decision date	Jan 30, 2026
Days to decision	305 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Asistan Medikal
Location	Oguzeli, Gaziantep, TR
Contact	Ibrahim Muhittin Tuzcu
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	510K FDA, Inc.
Contact	Lee Strong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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