

K243232 GripMateDec 2, 2024
54 days to decisionK243232 · Product code: **KZH** · General Hospital
Source: <https://www.510kdatabase.net/k243232/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Syringe Needle (KZH)
Date received	Oct 9, 2024
Decision date	Dec 2, 2024
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Synthon Hispania S.L.
Location	Sant Boi De Llobregat, ES
Contact	Ana Miralles
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Lachman Consultant Services, Inc.
Contact	Rebecca (Becky) Welton

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243232/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026