FDA 510(k) Premarket Notification

K243232 GripMate

CLEARED

Dec 2, 2024
54 days to decision

K243232 · 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