

K222689 Mallya Injection Pen Adapter (Mallya® for Solostar®)Dec 5, 2022
90 days to decisionK222689 · Product code: **QOG** · General Hospital
Source: <https://www.510kdatabase.net/k222689/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injection Data Capture Device (QOG)
Date received	Sep 6, 2022
Decision date	Dec 5, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biocorp Production
Location	Issoire, FR
Contact	Alexia Garin
510(k) history	4 submissions · 4 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	P/L Biomedical
Contact	Lee Leichter

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222689/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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