

**K203792 Insupen Pen needle, Insupen ORIGINAL Pen Needle,
Insupen ADVANCED pen needle**Jan 20, 2023
753 days to decisionK203792 · Product code: FMI · General Hospital
Source: <https://www.510kdatabase.net/k203792/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Dec 28, 2020
Decision date	Jan 20, 2023
Days to decision	753 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pikdare Spa
Location	Casnate Con Bernate, IT
Contact	Roberta Zanoni
510(k) history	2 submissions · 2 cleared · 2022-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203792/> 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 26, 2026