

K230070 MESORAM® Hypodermic Needle (710301)Oct 5, 2023
268 days to decisionK230070 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k230070/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 10, 2023
Decision date	Oct 5, 2023
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	MESORAM® Hypodermic Needle (710302); MESORAM® Hypodermic Needle (712305); MESORAM® Hypodermic Needle (712315); MESORAM® Hypodermic Needle (710303); MESORAM® Hypodermic Needle (710307); MESORAM® Hypodermic Needle (710306); MESORAM® Hypodermic Needle (712308); MESORAM® Hypodermic Needle (712318); MESORAM® Hypodermic Needle (712303); MESORAM® Hypodermic Needle (712307); MESORAM® Hypodermic Needle (712306); MESORAM® Hypodermic Needle (812400); MESORAM®

APPLICANT

Company	Promamedical, Inc.
Location	Miami, FL, US
Contact	Christian Wehrenpfenning
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Nilo Medical Consulting Group, LLC
Contact	Michael Nilo

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

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