FDA 510(k) Premarket Notification

K233764 SSS-NX (Serum Substitute Supplement-NX)

CLEARED

Apr 24, 2024
152 days to decision

K233764 · Product code: **MQL** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k233764/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Nov 24, 2023
Decision date	Apr 24, 2024
Days to decision	152 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fujifilm Irvine Scientific**
Location	Santa Ana, CA, US
Contact	Cindy Kha
510(k) history	4 submissions · 4 cleared · 2023-2025