FDA 510(k) Premarket Notification

K240605 Ultra RapidWarm™ Blast

CLEARED

Aug 7, 2024
156 days to decision

K240605 · Product code: **MQL** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k240605/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Mar 4, 2024
Decision date	Aug 7, 2024
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vitrolife Sweden AB**
Location	Ringoes, NJ, US
Contact	Nina Arvidsson
510(k) history	38 submissions · 38 cleared · 2000-2025