FDA 510(k) Premarket Notification

K221547 InActiv Blue

CLEARED

Jun 11, 2024
746 days to decision

K221547 · Product code: **QBD** · Microbiology
Source: https://www.510kdatabase.net/k221547/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Microbial Nucleic Acid Storage And Stabilization Device (QBD)
Date received	May 27, 2022
Decision date	Jun 11, 2024
Days to decision	746 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fertipro NV**
Location	Irvine, CA, US
Contact	Liesbeth Faes
Website	https://fertipro.com/
510(k) history	4 submissions · 4 cleared · 2006-2025

Fertipro NV is an independent manufacturer of in vitro diagnostics and cell culture media for assisted reproductive technologies and male infertility diagnosis. Founded in 1992, the company operates a state-of-the-art manufacturing facility in Beernem, Belgium, with FDA registration in Irvine, US. Fertipro holds ISO 13485 certification and participates in the MDSAP program. The company has received FDA 510(k) clearances from total submissions since 2006. Obstetrics & Gynecology devices dominate the regulatory portfolio, representing 75% of submissions. The latest clearanc...

REGULATORY CONSULTANT

Consulting firm	**Ducks IN A Row Compliance, LLC**
Contact	Gregor P Kleinert

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