FDA 510(k) Premarket Notification

K190152 Vit Kit- Freeze NX and Vit Kit- Warm NX

CLEARED

Jun 21, 2019
142 days to decision

K190152 · Product code: **MQL** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k190152/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Jan 30, 2019
Decision date	Jun 21, 2019
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fujifilm Irvine Scientific, Inc.**
Location	Santa Ana, CA, US
Contact	Jayme Yamaguchi-Owens
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Fujifilm Irine Scientific, Inc.**
Contact	Jayme Yamaguchi-Owens

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