FDA 510(k) Premarket Notification

K200815 VitriGuard

CLEARED

Jun 25, 2020
87 days to decision

K200815 · Product code: **MQK** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k200815/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Labware, Assisted Reproduction (MQK)
Date received	Mar 30, 2020
Decision date	Jun 25, 2020
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Origio A/S**
Location	San Diego, CA, US
Contact	Christine Kupchick
510(k) history	14 submissions · 14 cleared · 2010-2020

REGULATORY CONSULTANT

Consulting firm	**CooperSurgical, Inc.**
Contact	Christine Kupchick

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