FDA 510(k) Premarket Notification

K162833 VitriGuard

CLEARED

Feb 16, 2017
128 days to decision

K162833 · Product code: **MQK** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k162833/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Labware, Assisted Reproduction (MQK)
Date received	Oct 11, 2016
Decision date	Feb 16, 2017
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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