FDA 510(k) Premarket Notification

K162640 iVitri EZ

CLEARED

Jun 30, 2017
281 days to decision

K162640 · Product code: **MQK** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k162640/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Labware, Assisted Reproduction (MQK)
Date received	Sep 22, 2016
Decision date	Jun 30, 2017
Days to decision	281 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Reprobitech Corp.**
Location	New Hyde Park, NY, US
Contact	Huai L. Feng
510(k) history	2 submissions · 2 cleared · 2017-2018