FDA 510(k) Premarket Notification

K182274 Orbit Subretinal Delivery System

CLEARED

Nov 20, 2018
90 days to decision

K182274 · Product code: **FMF** · Ophthalmic
Source: https://www.510kdatabase.net/k182274/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Aug 22, 2018
Decision date	Nov 20, 2018
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Orbit Biomedical, Inc.**
Location	Ambler, PA, US
Contact	Michael Keane
510(k) history	1 submissions · 0 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	**Clinreg Consulting Services, Inc.**
Contact	Judy F. Gordon

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