FDA 510(k) Premarket Notification

K200325 Orbit Subretinal Delivery System

CLEARED

Jul 14, 2020
155 days to decision

K200325 · Product code: **FMF** · Ophthalmic
Source: https://www.510kdatabase.net/k200325/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Feb 10, 2020
Decision date	Jul 14, 2020
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Orbit Biomedical**
Location	Ambler, PA, US
Contact	Stacey Backlund
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Clinreg Cnsulting Services, Inc.**
Contact	Debe Deck

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