

K200325 Orbit Subretinal Delivery SystemJul 14, 2020
155 days to decisionK200325 · 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 Consulting Services, Inc.
Contact	Debe Deck

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

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