

K221540 Synexis Sphere RxJun 14, 2023
383 days to decisionK221540 · Product code: **FRA** · General HospitalSource: <https://www.510kdatabase.net/k221540/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Purifier, Air, Ultraviolet, Medical (FRA)
Date received	May 27, 2022
Decision date	Jun 14, 2023
Days to decision	383 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Synexis, LLC
Location	Lenexa, KS, US
Contact	Athena Hansen
510(k) history	1 submissions · 1 cleared · 2023-2023

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