

K212824 Bluezone Model RX-450 Air PurifierFeb 17, 2022
167 days to decisionK212824 · Product code: **FRA** · General Hospital
Source: <https://www.510kdatabase.net/k212824/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Purifier, Air, Ultraviolet, Medical (FRA) |
| Date received | Sep 3, 2021 |
| Decision date | Feb 17, 2022 |
| Days to decision | 167 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Bluezone Products, Inc. |
| Location | Woburn, MA, US |
| Contact | Karen Benedek |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |

REGULATORY CONSULTANT

| | |
|-----------------|---|
| Consulting firm | O&apos;Connell Regulatory Consultant, Inc. |
| Contact | Maureen O'Connell |

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

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