FDA 510(k) Premarket Notification

K242604 Helios+ UV-C System

CLEARED

May 27, 2025
270 days to decision

K242604 · Product code: **QXJ** · General Hospital
Source: https://www.510kdatabase.net/k242604/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Whole Room Microbial Reduction Device (QXJ)
Date received	Aug 30, 2024
Decision date	May 27, 2025
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Preventamed Technologies, Inc. Dba Surfacide Manufacturing**
Location	Waukesha, WI, US
Contact	Jeffry Veenhuis
510(k) history	1 submissions · 1 cleared · 2025-2025