FDA 510(k) Premarket Notification

K243815 SoClean 3+

CLEARED

Oct 10, 2025
303 days to decision

K243815 · Product code: **QXQ** · General Hospital
Source: https://www.510kdatabase.net/k243815/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Accessory Microbial Reduction Device. (QXQ)
Date received	Dec 11, 2024
Decision date	Oct 10, 2025
Days to decision	303 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Soclean, Inc.**
Location	Peterborough, NH, US
Contact	George Peters
510(k) history	2 submissions · 1 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	John J. Smith

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