

K231256 Carecube Negative Pressure Isolation Chamber

Jan 3, 2024
247 days to decision

K231256 · Product code: **LGM** · General Hospital
Source: <https://www.510kdatabase.net/k231256/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chamber, Patient Isolation (LGM)
Date received	May 1, 2023
Decision date	Jan 3, 2024
Days to decision	247 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Carecubes, Inc.
Location	San Francisco, CA, US
Contact	Alexander Laskey
510(k) history	1 submissions · 1 cleared · 2024-2024

CLINICAL EVIDENCE - NCT05468723

Evaluating Patient Comfort and Environmental Conditions in the Carecube Negative Pressure Isolation Chamber.1

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	11 patients (actual)
Study sites	1 site
Condition studied	Infectious Diseases
Study type	Observational
Completion date	Jun 18, 2022
Sponsor	Carecubes, Inc. (Industry)

Primary outcome

Body Temperature

Secondary outcome

Comfort

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05468723