FDA 510(k) Premarket Notification

K213335 Capsule Surveillance System

CLEARED

Jan 14, 2022
100 days to decision

K213335 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k213335/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Oct 6, 2021
Decision date	Jan 14, 2022
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Capsule Surveillance Technologies, Sas /Capsule Tech, Inc.**
Location	Andover, MA, US
Contact	Peter Kelley
510(k) history	1 submissions · 1 cleared · 2022-2022