FDA 510(k) Premarket Notification

K232495 Sempulse Halo Vital Signs Monitor

CLEARED

May 16, 2024
273 days to decision

K232495 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k232495/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Aug 17, 2023
Decision date	May 16, 2024
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Sempulse Corporation**
Location	San Marcos, TX, US
Contact	Matt Barrera
510(k) history	1 submissions · 1 cleared · 2024-2024