FDA 510(k) Premarket Notification

CLEARED

K232048 Cogent™ Hemodynamic Monitoring System

Dec 20, 2023
163 days to decision

K232048 · Product code: **DXG** · Cardiovascular
Source: https://www.510kdatabase.net/k232048/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Jul 10, 2023
Decision date	Dec 20, 2023
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Cogent™ HMS

APPLICANT

Company	**Icu Medical**
Location	Lake Forest, IL, US
Contact	Diane Stockman
510(k) history	5 submissions · 5 cleared · 2017-2023