FDA 510(k) Premarket Notification

CLEARED

K071805 NETGUARD AUTOMATED CLINICIAN ALERT SYSTEM, MODEL 0998-00-1600-XX

Sep 25, 2007
85 days to decision

K071805 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k071805/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Jul 2, 2007
Decision date	Sep 25, 2007
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Datascope Corp.**
Location	Mchenry, IL, US
Contact	KATHLEEN KRAMER
510(k) history	136 submissions · 135 cleared · 1976-2019