FDA 510(k) Premarket Notification

K002248 DINAMAP PRO 1000 MONITOR, MODEL 1000

CLEARED

Sep 21, 2000
58 days to decision

K002248 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k002248/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jul 25, 2000
Decision date	Sep 21, 2000
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Critikon Company, LLC**
Location	Mchenry, IL, US
Contact	THOMAS J ENGLISH
510(k) history	51 submissions · 51 cleared · 1979-2000