FDA 510(k) Premarket Notification

K963198 PS-41 6M PATIENT SIMULATOR

CLEARED

Mar 5, 1997
202 days to decision

K963198 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k963198/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Aug 15, 1996
Decision date	Mar 5, 1997
Days to decision	202 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Metron U.S., Inc.**
Location	Grand Rapids, MI, US
Contact	JIM QUINN
510(k) history	4 submissions · 4 cleared · 1997-1998