FDA 510(k) Premarket Notification

K973318 MOBIMED SYSTEM, (PEGASUS AND POLARIS)

CLEARED

Feb 19, 1998
168 days to decision

K973318 · Product code: **MSX** · Cardiovascular
Source: https://www.510kdatabase.net/k973318/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Network And Communication, Physiological Monitors (MSX)
Date received	Sep 4, 1997
Decision date	Feb 19, 1998
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ortivus Us, Inc.**
Location	Minneapolis,, MN, US
Contact	CONSTANCE G BUNDY
510(k) history	1 submissions · 1 cleared · 1998-1998