FDA 510(k) Premarket Notification

K170032 QMAPP Amplifier

CLEARED

Sep 8, 2017
247 days to decision

K170032 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k170032/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jan 4, 2017
Decision date	Sep 8, 2017
Days to decision	247 days
Third-party review	No
Summary / Statement	Summary
Other names	QMAPP Hemodynamic Monitoring System; QMAPP PCM; QMAPP GO; QMAPP EP

APPLICANT

Company	**Fysicon BV**
Location	Oss, NL
Contact	C.W.A (Eric) Van Antwerpen
510(k) history	2 submissions · 2 cleared · 2017-2025