FDA 510(k) Premarket Notification

K172862 Portable ECG Monitor (ECG3)

CLEARED

Jul 24, 2018
307 days to decision

K172862 · Product code: **DSH** · Cardiovascular
Source: https://www.510kdatabase.net/k172862/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Sep 20, 2017
Decision date	Jul 24, 2018
Days to decision	307 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Andon Health Co, Ltd.**
Location	Tiajin, CN
Contact	Liu Yi
510(k) history	92 submissions · 92 cleared · 2008-2025