FDA 510(k) Premarket Notification

CLEARED

K170565 LifeWatch Mobile Cardiac Telemetry 3 Lead LifeWatch MCT 3L

Aug 1, 2017
155 days to decision

K170565 · Product code: **QYX** · Cardiovascular
Source: https://www.510kdatabase.net/k170565/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Outpatient Cardiac Telemetry (QYX)
Date received	Feb 27, 2017
Decision date	Aug 1, 2017
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lifewatch Services, Inc.**
Location	Rosemont, IL, US
Contact	Stefanie Martinez-Koenig
510(k) history	1 submissions · 1 cleared · 2017-2017