K101571 XPER INFORMATION MANAGEMENT AND FLEX CARDIO PHYSIOMONITORING SYSTEMS

CLEARED

Oct 26, 2010
144 days to decision

K101571 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k101571/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jun 4, 2010
Decision date	Oct 26, 2010
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Witt Biomedical Corp**
Location	Melbourne, FL, US
Contact	JAMES LUKER
510(k) history	5 submissions · 5 cleared · 2004-2010