FDA 510(k) Premarket Notification

K160349 Electronic Sphygmomanometer

CLEARED

Nov 3, 2016
269 days to decision

K160349 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k160349/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Feb 8, 2016
Decision date	Nov 3, 2016
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Guangdong Biolight Meditech Co., Ltd.**
Location	Shanghai, CN
Contact	Liang Jin
510(k) history	21 submissions · 21 cleared · 2008-2019