FDA 510(k) Premarket Notification

CLEARED

K093102 AMBULATORY BLOOD PRESSURE MONITOR, MODELS FB-270 AND DS-270

Jun 3, 2010
245 days to decision

K093102 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k093102/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Oct 1, 2009
Decision date	Jun 3, 2010
Days to decision	245 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nihon Seimitsu Sokki Co., Ltd.**
Location	Shibukawa-Shi, Gunma-Ken, JP
Contact	KOJI KUBO
510(k) history	21 submissions · 21 cleared · 1985-2012