FDA 510(k) Premarket Notification

K101123 NEXFIN MODEL 2

CLEARED

Oct 28, 2010
189 days to decision

K101123 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k101123/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Apr 22, 2010
Decision date	Oct 28, 2010
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bmeye B.V.**
Location	Westford, MA, US
Contact	WILLIAM F GREENROSE
510(k) history	2 submissions · 2 cleared · 2007-2010