FDA 510(k) Premarket Notification

K173916 Finapres Nova Noninvasive Hemodynamic Monitor

CLEARED

Nov 6, 2018
319 days to decision

K173916 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k173916/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Dec 22, 2017
Decision date	Nov 6, 2018
Days to decision	319 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Finapres Medical Systems B.V.**
Location	Amsterdam Zo, NL
Contact	Iris van Uitert
510(k) history	4 submissions · 4 cleared · 2007-2018