FDA 510(k) Premarket Notification

CLEARED

K173036 North-vision Multi-parameter Patient Monitor

Dec 21, 2018
449 days to decision

K173036 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k173036/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Sep 28, 2017
Decision date	Dec 21, 2018
Days to decision	449 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**North-Vision Tech., Inc.**
Location	Hsinchu City, TW
Contact	Albert Huang
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	**Pan-America Hyperbarics, Inc.**
Contact	Shin-Ban Tsai

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov