FDA 510(k) Premarket Notification

K010424 NEXAN SYSTEM, MODEL NX-301

CLEARED

Sep 4, 2001
203 days to decision

K010424 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k010424/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Feb 13, 2001
Decision date	Sep 4, 2001
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nexan, Ltd.**
Location	Rockville, MD, US
Contact	DAVID L WEST
510(k) history	2 submissions · 2 cleared · 2000-2001