FDA 510(k) Premarket Notification

K032888 CREATION NM DIAGNOSTIC CATHETERS

CLEARED

Feb 24, 2004
161 days to decision

K032888 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k032888/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Sep 16, 2003
Decision date	Feb 24, 2004
Days to decision	161 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Neich Medical (Shenzhen) Company Limited**
Location	Shenzhen, CN
Contact	RAYMOND LIN
510(k) history	2 submissions · 2 cleared · 2003-2004