FDA 510(k) Premarket Notification

K003748 TIANXIE

CLEARED

Jan 26, 2001
53 days to decision

K003748 · Product code: **MQX** · General Hospital
Source: https://www.510kdatabase.net/k003748/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Acupuncture, Single Use (MQX)
Date received	Dec 4, 2000
Decision date	Jan 26, 2001
Days to decision	53 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Suzhou Tianyi Acupuncture Instruments Co., Ltd.**
Location	Costa Mesa, CA, US
Contact	HENRY WOO
510(k) history	1 submissions · 1 cleared · 2001-2001