FDA 510(k) Premarket Notification

K140228 DISPOSABLE TRACHEAL TUBE

CLEARED

Dec 18, 2014
322 days to decision

K140228 · Product code: **BTR** · Anesthesiology
Source: https://www.510kdatabase.net/k140228/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheal (w/wo Connector) (BTR)
Date received	Jan 30, 2014
Decision date	Dec 18, 2014
Days to decision	322 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Suzhou Weikang Medical Apparatus Co., Ltd.**
Location	Guangzhou, Guangdong, CN
Contact	MIKE GU
510(k) history	2 submissions · 2 cleared · 2014-2015

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k140228/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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