FDA 510(k) Premarket Notification

K190274 Endotracheal Tube

CLEARED

Jul 30, 2019
172 days to decision

K190274 · Product code: **BTR** · Anesthesiology
Source: https://www.510kdatabase.net/k190274/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheal (w/wo Connector) (BTR)
Date received	Feb 8, 2019
Decision date	Jul 30, 2019
Days to decision	172 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tianjin Medis Medical Device Co., Ltd.**
Location	Tianjin City, CN
Contact	Yongzhi Wu
510(k) history	3 submissions · 3 cleared · 2017-2019

REGULATORY CONSULTANT

Consulting firm	**Mid-Link Consulting Co, Ltd.**
Contact	Diana Hong

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