FDA 510(k) Premarket Notification

CLEARED

K213028 Tenax Laser Resistant Endotracheal Tube

Oct 21, 2021
30 days to decision

K213028 · Product code: **BTR** · Anesthesiology
Source: https://www.510kdatabase.net/k213028/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tube, Tracheal (w/wo Connector) (BTR)
Date received	Sep 21, 2021
Decision date	Oct 21, 2021
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bryan Medical, Inc.**
Location	Cincinnati, OH, US
Contact	Andrew J Georgilis
510(k) history	3 submissions · 3 cleared · 2015-2021

REGULATORY CONSULTANT

Consulting firm	**AlvaMed, Inc.**
Contact	Martha Kamrow Russell

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