

**K213028 Tenax Laser Resistant Endotracheal Tube**Oct 21, 2021  
30 days to decisionK213028 · 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	<b>Bryan Medical, Inc.</b>
Location	Cincinnati, OH, US
Contact	Andrew J Georgilis
510(k) history	3 submissions · 3 cleared · 2015-2021

**REGULATORY CONSULTANT**

---

Consulting firm	<b>AlvaMed, Inc.</b>
Contact	Martha Kamrow Russell

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213028/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 26, 2026