

**K190274 Endotracheal Tube**Jul 30, 2019  
172 days to decisionK190274 · Product code: **BTR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k190274/>**SUBMISSION DETAILS**

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|                       |                                       |
|-----------------------|---------------------------------------|
| 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**

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

**REGULATORY CONSULTANT**

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|-----------------|-------------------------------------|
| Consulting firm | <b>Mid-Link Consulting Co, Ltd.</b> |
| Contact         | Diana Hong                          |

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

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