

**K221206 Compass Steerable Needle**Aug 25, 2022  
121 days to decisionK221206 · Product code: **KTI** · Anesthesiology  
Source: <https://www.510kdatabase.net/k221206/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Bronchoscope Accessory (KTI)       |
| Date received         | Apr 26, 2022                       |
| Decision date         | Aug 25, 2022                       |
| Days to decision      | 121 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Serpex Medical, Inc.</b>           |
| Location       | Santa Clara, CA, US                   |
| Contact        | Sasha Schrode                         |
| 510(k) history | 3 submissions · 3 cleared · 2022-2025 |

**REGULATORY CONSULTANT**

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|-----------------|----------------------------------|
| Consulting firm | <b>Honkanen Consulting, Inc.</b> |
| Contact         | Laurie Lewandowski               |

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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