

**K220218 Siren SGT**May 18, 2022  
112 days to decisionK220218 · Product code: **KNT** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k220218/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)              |
| Submission type       | Traditional                                     |
| Device classification | Tubes, Gastrointestinal (and Accessories) (KNT) |
| Date received         | Jan 26, 2022                                    |
| Decision date         | May 18, 2022                                    |
| Days to decision      | 112 days  |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Tools For Surgery, LLC</b>         |
| Location       | Stony Brook, NY, US                   |
| Contact        | Arnold R. Leiboff                     |
| 510(k) history | 4 submissions · 4 cleared · 2004-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220218/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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