

K201808 X-Tack Endoscopic HeliX Tacking SystemDec 15, 2020
167 days to decisionK201808 · Product code: **PKL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k201808/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Hemostatic Metal Clip For The Gi Tract (PKL) |
| Date received | Jul 1, 2020 |
| Decision date | Dec 15, 2020 |
| Days to decision | 167 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Apollo Endosurgery, Inc. |
| Location | Austin, TX, US |
| Contact | Natalie Allen |
| 510(k) history | 12 submissions · 10 cleared · 2008-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201808/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026