

**K191736 da Vinci X/Xi 8mm Endoscope Plus, 0, da Vinci X/Xi
8mm Endoscope Plus, 30**Jul 26, 2019
28 days to decisionK191736 · Product code: **NAY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k191736/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, Surgical, Computer Controlled Instrument (NAY) |
| Date received | Jun 28, 2019 |
| Decision date | Jul 26, 2019 |
| Days to decision | 28 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Intuitive Surgical |
| Location | Sunnyvale, CA, US |
| Contact | Vishal Kanani |
| Website | http://www.intuitivesurgical.com |
| 510(k) history | 16 submissions · 15 cleared · 2014-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191736/> 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