

**K213392 INLIANT Surgical Navigation System**Feb 22, 2022  
130 days to decisionK213392 · Product code: **PLV** · Dental  
Source: <https://www.510kdatabase.net/k213392/>**SUBMISSION DETAILS**

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|                       |                                     |
|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional                         |
| Device classification | Dental Stereotaxic Instrument (PLV) |
| Date received         | Oct 15, 2021                        |
| Decision date         | Feb 22, 2022                        |
| Days to decision      | 130 days                            |
| Third-party review    | No                                  |
| Combination product   | No                                  |
| PCCP authorized       | No                                  |
| Summary / Statement   | Summary                             |

**APPLICANT**

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|----------------|---|
| Company        | <b>Navigate Surgical Technologies, Inc.</b> |
| Location       | Vancouver, CA                               |
| Contact        | Marty Dymek                                 |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022       |

**REGULATORY CONSULTANT**

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|-----------------|----------------------------|
| Consulting firm | <b>Pamela Buckman, Msn</b> |
| Contact         | Pamela Buckman             |

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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