

K193403 UroNav SystemDec 27, 2019
21 days to decisionK193403 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k193403/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | Dec 6, 2019 |
| Decision date | Dec 27, 2019 |
| Days to decision | 21 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Invivo Corporation |
| Location | Pewaukee, WI, US |
| Contact | Kym Rupp |
| 510(k) history | 29 submissions · 29 cleared · 2005-2021 |

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