

K011971 NAVIGUS TRAJECTORY GUIDE BIOPSY KIT, MODELS BK-7000 AND 8000

Aug 3, 2001
39 days to decision

K011971 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k011971/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Neurological Stereotaxic Instrument (HAW) |
| Date received | Jun 25, 2001 |
| Decision date | Aug 3, 2001 |
| Days to decision | 39 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Image-Guided Neurologics, Inc. |
| Location | Melbourne, FL, US |
| Contact | DAVID M LEE |
| 510(k) history | 22 submissions · 22 cleared · 1999-2005 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k011971/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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