

K033621 NDI PASSIVE SPHERESJan 27, 2004
70 days to decisionK033621 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k033621/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Neurological Stereotaxic Instrument (HAW) |
| Date received | Nov 18, 2003 |
| Decision date | Jan 27, 2004 |
| Days to decision | 70 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Northern Digital, Inc. |
| Location | Dundas, CA |
| Contact | NANCY RUTH |
| 510(k) history | 1 submissions · 1 cleared · 2004-2004 |

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