

**K955335 DISPOSABLE HYPODERMIC MONOPOLAR NEEDLE
RECORDING ELECTRODE**Jan 29, 1996
70 days to decisionK955335 · Product code: **IKT** · Neurology
Source: <https://www.510kdatabase.net/k955335/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrode, Needle, Diagnostic Electromyograph (IKT) |
| Date received | Nov 20, 1995 |
| Decision date | Jan 29, 1996 |
| Days to decision | 70 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Chalgren Enterprises, Inc. |
| Location | Gilroy, CA, US |
| Contact | RICHARD KAISER |
| 510(k) history | 21 submissions · 21 cleared · 1989-1999 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k955335/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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