FDA 510(k) Premarket Notification

# K944615 A620 EEG

**CLEARED**

Sep 18, 1995
363 days to decision

K944615 · Product code: **HCC** · Neurology
Source: https://www.510kdatabase.net/k944615/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, Biofeedback (HCC) |
| Date received | Sep 20, 1994 |
| Decision date | Sep 18, 1995 |
| Days to decision | 363 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Stoelting Co.** |
| Location | Wood Dale, IL, US |
| Contact | SAID EL-DINARY |
| 510(k) history | 4 submissions · 4 cleared · 1995-2001 |