

**K092973 DISPOSABLE AND REUSABLE CONCENTRIC
NEEDLES / DISPOSABLE AND REUSABLE MONOPOLAR
NEEDLE**Oct 7, 2010
377 days to decisionK092973 · Product code: **IKT** · Neurology
Source: <https://www.510kdatabase.net/k092973/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrode, Needle, Diagnostic Electromyograph (IKT) |
| Date received | Sep 25, 2009 |
| Decision date | Oct 7, 2010 |
| Days to decision | 377 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Bionen S.A.S. |
| Location | Carmel, IN, US |
| Contact | Allison Scott |
| 510(k) history | 1 submissions · 1 cleared · 2010-2010 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092973/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 20, 2026