

**K040639 ISURG DISPOSABLE SUBDERMAL NEEDLE  
ELECTRODE**May 21, 2004  
72 days to decisionK040639 · Product code: **GXZ** · Neurology  
Source: <https://www.510kdatabase.net/k040639/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Electrode, Needle (GXZ)            |
| Date received         | Mar 10, 2004                       |
| Decision date         | May 21, 2004                       |
| Days to decision      | 72 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Isurgical</b>                      |
| Location       | Mundelein, IL, US                     |
| Contact        | KEN LEISER                            |
| 510(k) history | 1 submissions · 1 cleared · 2004-2004 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040639/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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