

**K161566 DMS Disposable Subdermal Needle Electrodes**Dec 21, 2016  
198 days to decisionK161566 · Product code: **GXZ** · Neurology  
Source: <https://www.510kdatabase.net/k161566/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Electrode, Needle (GXZ)            |
| Date received         | Jun 6, 2016                        |
| Decision date         | Dec 21, 2016                       |
| Days to decision      | 198 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Daehan Medical Systems Co., Ltd.</b> |
| Location       | Siheung-City, KR                        |
| Contact        | Dong Cheul Kim                          |
| 510(k) history | 3 submissions · 3 cleared · 2016-2019   |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161566/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026