

**K150789 SPINAUT-E, SPINAUT-I**Mar 1, 2016  
342 days to decisionK150789 · Product code: **BSO** · Anesthesiology  
Source: <https://www.510kdatabase.net/k150789/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | Catheter, Conduction, Anesthetic (BSO) |
| Date received         | Mar 25, 2015                           |
| Decision date         | Mar 1, 2016                            |
| Days to decision      | 342 days                               |
| Third-party review    | No                                     |
| Summary / Statement   | Summary                                |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Imedicom Co., Ltd.</b>             |
| Location       | Gunpo-Si, KR                          |
| Contact        | Bonggu Ha                             |
| 510(k) history | 6 submissions · 6 cleared · 2016-2019 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150789/> 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