

**K250689 CloudTMS Edge**Sep 14, 2025  
192 days to decisionK250689 · Product code: **OBP** · Neurology  
Source: <https://www.510kdatabase.net/k250689/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | Transcranial Magnetic Stimulator (OBP) |
| Date received         | Mar 6, 2025                            |
| Decision date         | Sep 14, 2025                           |
| Days to decision      | 192 days                               |
| Third-party review    | No                                     |
| Combination product   | No                                     |
| PCCP authorized       | No                                     |
| Summary / Statement   | Summary                                |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Teleemg, LLC</b>                   |
| Location       | Woburn, MA, US                        |
| Contact        | Jabre Joe                             |
| 510(k) history | 5 submissions · 5 cleared · 2016-2025 |

**REGULATORY CONSULTANT**

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|-----------------|-----------------------|
| Consulting firm | <b>Makromed, Inc.</b> |
| Contact         | Ashar Barry           |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250689/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026