

K203827 REMIMar 29, 2021
90 days to decisionK203827 · Product code: **OMC** · Neurology
Source: <https://www.510kdatabase.net/k203827/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Reduced- Montage Standard Electroencephalograph (OMC) |
| Date received | Dec 29, 2020 |
| Decision date | Mar 29, 2021 |
| Days to decision | 90 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Eptel, Inc. |
| Location | Salt Lake City, UT, US |
| Contact | Mark Lehmkuhle |
| 510(k) history | 4 submissions · 4 cleared · 2021-2024 |

REGULATORY CONSULTANT

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|-----------------|-----------------|
| Consulting firm | leanRAQA |
| Contact | John Pappan |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203827/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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