

**K080375 RMX PHYSIOLOGICAL DATA RECORDER**Sep 2, 2008  
203 days to decisionK080375 · Product code: **MNR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k080375/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Ventilatory Effort Recorder (MNR)  |
| Date received         | Feb 12, 2008                       |
| Decision date         | Sep 2, 2008                        |
| Days to decision      | 203 days                           |
| Third-party review    | Yes                                |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>S.L.P. , Ltd.</b>                  |
| Location       | Tel-Aviv, IL                          |
| Contact        | NOAM HADAS                            |
| 510(k) history | 5 submissions · 5 cleared · 2004-2020 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080375/> 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 15, 2026