

K150419 miraDry System MD4000Jun 19, 2015
121 days to decisionK150419 · Product code: **OUB** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k150419/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Instrument For Treatment Of Hyperhidrosis (OUB) |
| Date received | Feb 18, 2015 |
| Decision date | Jun 19, 2015 |
| Days to decision | 121 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Miramar Labs, Inc. |
| Location | Menlo Park, CA, US |
| Contact | KATHY O'SHAUGHNESSY |
| 510(k) history | 6 submissions · 6 cleared · 2009-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150419/> Data sourced from FDA 510(k) public records (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. - Generated May 30, 2026