

K180885 HairMax LaserJun 20, 2018
77 days to decisionK180885 · Product code: **OAP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k180885/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Laser, Comb, Hair (OAP) |
| Date received | Apr 4, 2018 |
| Decision date | Jun 20, 2018 |
| Days to decision | 77 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Lexington International, LLC |
| Location | Washington, DC, US |
| Contact | David Michaels |
| 510(k) history | 8 submissions · 8 cleared · 2007-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180885/> 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