

K252531 Myosa (S1H, S1, S2, S3, S1M, S2M)Mar 2, 2026
202 days to decisionK252531 · Product code: **LRK** · Dental
Source: <https://www.510kdatabase.net/k252531/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, Anti-snoring (LRK) |
| Date received | Aug 12, 2025 |
| Decision date | Mar 2, 2026 |
| Days to decision | 202 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | Myosa for Snorers (S1, S1M, S2) |

APPLICANT

| | |
|----------------|-----------------------------------------------------------------------|
| Company | Myofunctional Research Co. |
| Location | Helmsvale, AU |
| Contact | Vikas Kundu |
| Website | https://www.myoresearch.com |
| 510(k) history | 1 submissions · 1 cleared · 2026-2026 |

Myofunctional Research Co. develops intraoral appliance systems and education programs for treating breathing, myofunctional, and orthodontic disorders. The company operates with a manufacturing facility in Helmsvale, Australia, and serves dental and medical practitioners globally across more than 100 countries. The company has received FDA 510(k) clearance from total submission. Dental devices represent 100% of the company's regulatory submissions. The latest clearance was granted in 2026, confirming active regulatory engagement. MRC's product portfolio includes the Myos...

REGULATORY CONSULTANT

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|-----------------|---------------------------------|
| Consulting firm | Db a the Eyedeas Company |
| Contact | Colette Cozean |

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

Device record: <https://www.510kdatabase.net/k252531/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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