

K243990 BondEase 2 Topical Skin AdhesiveSep 19, 2025
267 days to decisionK243990 · Product code: **MPN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243990/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Tissue Adhesive For The Topical Approximation Of Skin (MPN) |
| Date received | Dec 26, 2024 |
| Decision date | Sep 19, 2025 |
| Days to decision | 267 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Optmed, Inc. |
| Location | New York, NY, US |
| Contact | Nitasha Yajnik |
| 510(k) history | 3 submissions · 3 cleared · 2015-2025 |

REGULATORY CONSULTANT

| | |
|-----------------|-------------|
| Consulting firm | RQM+ |
| Contact | Lucie Dalet |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243990/> 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 14, 2026