

K172010 gel-e BandageDec 7, 2017
157 days to decisionK172010 · Product code: **KGN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k172010/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Wound Dressing With Animal-derived Material(s) (KGN) |
| Date received | Jul 3, 2017 |
| Decision date | Dec 7, 2017 |
| Days to decision | 157 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Gel-E, Inc. (Formerly Remedium Technologies, Inc.) |
| Location | College Park, MD, US |
| Contact | Matthew Dowling |
| 510(k) history | 1 submissions · 1 cleared · 2017-2017 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172010/> 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 31, 2026