

K241080 Kerecis Parvus (50207)Aug 21, 2024
124 days to decisionK241080 · Product code: **KGN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k241080/>**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 | Apr 19, 2024 |
| Decision date | Aug 21, 2024 |
| Days to decision | 124 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Kerecis Limited |
| Location | Isafjordur, IS |
| Contact | William Kabitz |
| 510(k) history | 10 submissions · 10 cleared · 2013-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241080/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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