

**K192386 KeraStat Cream**Jul 16, 2020  
317 days to decisionK192386 · Product code: **KGN** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k192386/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Sep 3, 2019
Decision date	Jul 16, 2020
Days to decision	317 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Keranetics</b>
Location	Winston Salem, NC, US
Contact	Luke Burnett
510(k) history	1 submissions · 1 cleared · 2020-2020

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192386/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026