

**K213092 Cellusheet, Cellufil**Dec 15, 2021  
82 days to decisionK213092 · Product code: **KGN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213092/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Sep 24, 2021
Decision date	Dec 15, 2021
Days to decision	82 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Human Biosciences, Inc.</b>
Location	Oak Grove, MN, US
Contact	Jigar Patel
510(k) history	2 submissions · 2 cleared · 2012-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Methodize</b>
Contact	Jack Slovick

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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