

**K183190 NuStat**Sep 25, 2019  
310 days to decisionK183190 · Product code: **POD** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k183190/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Temporary, Internal Use Hemostatic (POD)
Date received	Nov 19, 2018
Decision date	Sep 25, 2019
Days to decision	310 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beeken Biomedical, LLC</b>
Location	Stoughton, MA, US
Contact	Richard A. Kendall
510(k) history	2 submissions · 2 cleared · 2016-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Alira Health</b>
Contact	Mary McNamara

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183190/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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