FDA 510(k) Premarket Notification

K183190 NuStat

CLEARED

Sep 25, 2019
310 days to decision

K183190 · Product code: **POD** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k183190/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Alira Health**
Contact	Mary McNamara

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