

K183622 NasalCEASE and BleedCEASEDec 2, 2019
341 days to decisionK183622 · Product code: **QSY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k183622/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Wound Dressing Without Thrombin Or Other Biologics (QSY)
Date received	Dec 26, 2018
Decision date	Dec 2, 2019
Days to decision	341 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Les Laboratoires Brothier S.A.
Location	Nanterre, FR
Contact	Christian Girardiere
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Heyer Regulatory Solutions, LLC
Contact	Sheila Hemeon-Heyer

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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