

K160578 Nustat XRJun 29, 2016
120 days to decisionK160578 · Product code: **QSY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k160578/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Wound Dressing Without Thrombin Or Other Biologics (QSY)
Date received	Mar 1, 2016
Decision date	Jun 29, 2016
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beeken Biomedical, LLC
Location	Stoughton, MA, US
Contact	DAN O'ARA
510(k) history	2 submissions · 2 cleared · 2016-2019

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