

K202830 Axiostat PatchApr 15, 2021
202 days to decisionK202830 · Product code: **QSY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k202830/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Wound Dressing Without Thrombin Or Other Biologics (QSY)
Date received	Sep 25, 2020
Decision date	Apr 15, 2021
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Advamedica, Inc.
Location	Cambridge, MA, US
Contact	Leo Mavely
510(k) history	5 submissions · 5 cleared · 2018-2023

REGULATORY CONSULTANT

Consulting firm	Matrix Medical Consulting, Inc.
Contact	Alan Donald

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202830/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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