

K253017 BloodSTOP iX Trauma Matrix (TM-iX-20)

Apr 30, 2026
223 days to decision

K253017 · Product code: **QSY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k253017/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Wound Dressing Without Thrombin Or Other Biologics (QSY)
Date received	Sep 19, 2025
Decision date	Apr 30, 2026
Days to decision	223 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lifescience Plus, Inc.
Location	Mystic, CT, US
Contact	Audrey Vitale
Website	https://lifescienceplus.com
510(k) history	4 submissions · 4 cleared · 2007-2026

Lifescience Plus, Inc. is a leader in advanced wound care technology. The company develops and markets innovative hemostatic and wound healing solutions. With a manufacturing facility in Mystic, the company focuses on acute and chronic wound care applications. Lifescience Plus has received FDA 510(k) clearances from total submissions since 2007. All cleared devices fall within General & Plastic Surgery. The company remains active, with its most recent clearance in 2026. The company’s product portfolio centers on hemostatic matrices and dressings. BloodSTOP® iX Advanced He...