FDA 510(k) Premarket Notification

K081183 WOUNDSTAT

CLEARED

Jun 19, 2008
55 days to decision

K081183 · Product code: **QSY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k081183/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Wound Dressing Without Thrombin Or Other Biologics (QSY)
Date received	Apr 25, 2008
Decision date	Jun 19, 2008
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Traumacure, Inc.**
Location	Washington, DC, US
Contact	CAMPBELL HUTTON
510(k) history	2 submissions · 2 cleared · 2007-2008

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k081183/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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