

K140387 Burn Resuscitation Decision Support System - Clinical (BRDSS-C)

Dec 23, 2014
312 days to decision

K140387 · Product code: PDT · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k140387/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Burn Resuscitation Decision Support Software (PDT)
Date received	Feb 14, 2014
Decision date	Dec 23, 2014
Days to decision	312 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	The Surgeon General, Department of the Army
Location	Fort Detrick, MD, US
Contact	KENNETH A BERTRAM, MD, PHD
510(k) history	2 submissions · 2 cleared · 2014-2015

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Device record: <https://www.510kdatabase.net/k140387/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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