FDA 510(k) Premarket Notification

K112598 AMERICAN SURGICAL COMPANY/ NEUROSURGICAL SPONGES (BRAND)

CLEARED

Jun 20, 2013
652 days to decision

K112598 · Product code: **HBA** · Neurology
Source: https://www.510kdatabase.net/k112598/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurosurgical Paddie (HBA)
Date received	Sep 7, 2011
Decision date	Jun 20, 2013
Days to decision	652 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**American Surgical Company, LLC**
Location	Lynn, MA, US
Contact	MICHAEL ALOUANE
510(k) history	2 submissions · 2 cleared · 2012-2013

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k112598/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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