FDA 510(k) Premarket Notification

K163461 Coolief* Cooled RF Probe

CLEARED

Apr 13, 2017
125 days to decision

K163461 · Product code: **GXI** · Neurology
Source: https://www.510kdatabase.net/k163461/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Probe, Radiofrequency Lesion (GXI)
Date received	Dec 9, 2016
Decision date	Apr 13, 2017
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Halyard Health, Inc.**
Location	Roswell, GA, US
Contact	Monica King
510(k) history	7 submissions · 6 cleared · 2015-2018

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k163461/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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